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FINAL REPORT

EXPERIMENTAL SYSTEM, AND ITS EVALUATION FOR THE CONTROL OF SURGICALLY INDUCTED INFECTIONS

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Prepared For:
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MARTIN MARIETTA
DENVER DIVISION

Contract NASW-2210
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FOREWORD

This document was prepared by the Martin Marietta Corporation under Contract NASW-2210, "Experimental System and Its Evaluation for the Control of Surgically Induced Infections" for the Applications Technology Office, National Aeronautics and Space Administration.

ABSTRACT

This report describes the effort accomplished under Contract NASW-2210 to design, fabricate, test and evaluate a prototype Experimental System for the control of surgically induced infections. The purpose of the Experimental System is to provide the cleanest possible environment within a hospital surgery room and eliminate contamination sources that could cause infections during surgery.

The system design is described. The system provides for a portable laminar flow clean room, a full bubble helmet system with associated communications and ventilation subsystems for operating room personnel, and surgical gowns that minimize the migration of bacteria. The development test results consisting of portability, laminar flowrate, air flow pattern, electrostatic buildup, noise level, ventilation, human factors, electrical and material compatibility tests are summarized.

The system was installed in St. Luke's Hospital, Denver, Colorado and used during actual surgery operations. The system was used for 73 operations using the total system and 160 operations using the laminar flow portion only. Data was collected of wound cultures and airborne contamination. This data was evaluated and compared with similar data of regular surgery rooms and surgery rooms using laminar flow only to determine the effectiveness of the system in reducing surgically induced infections.

With respect to airborne and wound contamination, the major reduction indicated is in the use of the laminar flow air filtration. The use of the total system including the helmets and gowns did not significantly reduce the wound contamination and airborne bacteria counts. No infections traceable to the surgical procedure were recorded for the operations performed to date, however, this is a preliminary value since infections could potentially occur up to two years following the surgery.

The conclusions are that the Experimental System is effective in reducing the airborne and wound contamination although the helmets and gowns may not be a significant part of this reduction. Definitive conclusions with regard to the infection rate cannot be made at this time. The recommendation is to continue the utilization of the System at St. Luke's and to continue to collect evaluation data.

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I. SUMMARY

The primary objective of the program was to evaluate the effectiveness of an experimental system in reducing surgically induced infections. In spite of advances in surgical procedures and antiseptic techniques, infection of surgical wounds still persist as a major area of concern. Some of the operations that span long time periods, require large incisions, involve large numbers of supporting personnel and equipment, expose the patient to an environment that can be conductive to infection unless the atmosphere is essentially free of particulate matter. The purpose of the Experimental System for the Control of Surgically Induced Infections (herein referred to as the System) was to provide a total system of equipment and procedures for establishing the cleanest possible environment within a hospital surgery room.

The System is comprised of: a portable clean room made up of a Class 100 (3.5 liter) horizontal laminar flow filter system and a transparent enclosure; a helmet system with associated communications and ventilation for operating room personnel; and surgical gowns made of materials that minimize the migration of bacteria.

The System was designed, developed, fabricated, and tested by Martin Marietta. At no cost to the NASA contract, St. Luke's Hospital used the System during actual surgery operations, collected bacteriological and infection data and provided a medical evaluation of the effectiveness of the System in reducing surgically induced infections.

The program was performed in a 12-month time span and accomplished in four tasks:

Task 1 - Configuration Selection

Task 2 - Equipment Specification and Assembly

Task 3 - Test

Task 4 - Experimental Data Collection and Evaluation

A. SYSTEM DESIGN

The portable clean room consists of a Class 100 (3.5 liter) horizontal laminar flow filter system and a transparent wall and ceiling enclosure. The filter system removes all airborne particulate

larger than 0.3 micron with an efficiency of 99.97 percent. Air flow through the enclosure is horizontal with a nominal velocity of 27.45 meters per minute (90 feet per minute) with a uniformity of plus or minus 6.10 meters per minute (20 feet per minute). The enclosure provides a 3.05 x 3.05 meter (10 x 10 feet) working area. The portable clean room is caster mounted and can be collapsed for storage into an approximate 1.5 x 3.4 meter (5 x 11 feet) floor space envelope. The portable clean room can also be disassembled and transferred to another room. The portable clean room allows the use of existing facility lighting.

Full bubble transparent helmets that attach to shoulder pad-harness assemblies are provided for each surgery team member. Communications headsets are provided for each surgery team member. The helmets are ventilated by a vacuum system that pulls air through a hole in the top of the helmet, out an umbilical at the rear of the shoulder pad and discharges into the main filter bank plenum. The ventilation system is provided with two vacuum blowers for redundancy. Normally, the ventilation system will supply 170-350 liters per minute (6.0-12.3 CFM) to each helmet depending upon the number of helmets in use with a minimum of 113 liters per minute (4.0 CFM) in the contingency mode (one blower failure).

The communications system which is powered by a 35 watt amplifier includes the helmet headsets, two external microphones for the circulating nurse and anaesthetist, and two external speakers. Volume controls are provided for each individual microphone, earphone and speaker.

The surgery gowns are a disposable split-back type constructed of a laminated gauze, cellulose and resin. The gowns are liquid repellant with low linting and static electricity characteristics. The material has been demonstrated to be an effective obstacle to the bacteria migration.

The electrical system is designed to meet the Class 1, Division 1, Group C electrical requirements of the National Electrical Code.

B. DEVELOPMENT AND ACCEPTANCE TESTS

The development tests were performed at the Martin Marietta Cold Flow facility. The tests were performed in a room that simulated the St. Luke's surgery room size and volume. In summary, the results are as follows:

Tests were performed on the portable clean room to demonstrate the assembly, collapsability, portability and storage. Collapsing,

relocating and storing within the surgery room can be accomplished in 12 minutes. The storage envelope dimensions are 1.65 meters (5 ft. 3-1/2 inches) x 4.24 meters (11 ft. 3-1/4 inches) x 2.62 meters (8 ft. 7-1/4 inches) high. The disassembly, transfer to another room, and reassembly were demonstrated.

The laminar air flow velocity profile within the enclosure was measured. In the undisturbed area of the enclosure the air flow met the Federal Standard 209a requirements of 27.45 meters (90 ft.) per minute $\pm$ 6.10 meters (20 ft.) per minute. Smoke tests with simulated surgery equipment and personnel in the enclosure did not indicate any detrimental air flow patterns.

Electrostatic buildup readings taken while installed in the test facility were high. Readings repeated after installation in the hospital which has a grounded floor indicated zero.

Noise level readings taken within the enclosure were 70-71 on the "A" scale and 57 db to 70 db at 500, 1000 and 2000 cycles. All readings were considered acceptable for the intended usage.

Helmet umbilical ventilation flow rates ranged from a maximum of 357 L/min (12.6 CFM) to 212 L/min (7.5 CFM) minimum depending upon the number of helmets on line. In the contingency mode of one ventilation blower off and six helmets on line, the minimum flow rate was 135 L/min (4.8 CFM). At normal flow rates of 170 L/min (6 CFM) and above the PCO_2 measured in the helmet was 0.4% or less. Increasing the ventilation to the gown decreased the temperature inside the gown 0.83-1.66 ^{o}K (1.5-3.0^{o}F).

A human factors evaluation by six test subjects did not reveal any significant objections. A loose fitting shoulder pad on a small person can be compensated by harness adjustments. Helmet visibility was good except some distortion was noted in the lower portion of the helmet. Noise of a person speaking inside the helmet was high but not objectionable after becoming accustomed to it.

Electrical subsystem operating voltages and currents were measured. Ground leakage currents could not be detected indicating a properly grounded system.

Material compatibility tests of hospital sterilization and cleaning procedures on materials used in the system were performed. No detrimental effects of the cleaning fluids on the material were noted. Steam sterilization corroded harness hardware; gas sterilization did not.

The conclusions were that the system as designed will perform the functions required for its intended use.

The preliminary acceptance tests were performed at Martin Marietta. The System was then disassembled, cleaned, packed, shipped and assembled in a St. Luke's surgery room. Final acceptance tests which were witnessed by the NASA-delegated AFPRO representative were performed and consisted of the following:

1. Visual inspection.

2. Portable clean room assembly demonstration test.

3. Laminar air flow and cleanliness test (St. Luke's only).

4. Helmet ventilation system test.

5. Functional demonstration test.

The laminar air flow and cleanliness test was performed by the Envirco (filter system manufacturer) local representative. A certification of conformance to Federal Standard 209a was obtained. A letter of acceptance by St. Luke's was also obtained.

C. DATA COLLECTION AND EVALUATION

The System was utilized by St. Luke's Hospital during actual orthopedic surgery operations. The System was used in two modes: a) one mode using the laminar flow filter system and enclosure only with regular surgical gown and mask attire, and b) using the total system including helmets and special gowns.

Prior to the patient arrival, the laminar flow filter system would be activated and the air within the surgery room circulated and filtered for several minutes. While the patient was being prepared, the surgery team scrubbed and donned surgery attire. When the helmets were used the shoulder pads and communications headsets were donned prior to scrubbing. Upon entry into the clean room, the helmets and gowns were donned. The surgery table was positioned parallel to the laminar flow stream with the surgery team positioned at each side of the table. The circulating nurse and anaethetist were always downstream of the patient with respect to air flow and were not required to wear helmets.

During surgery, wound cultures were taken. Both deep wound and superficial wound cultures were taken. Also, airborne contamination

samples were periodically taken. The airborne sampler sensor was positioned immediately downstream of the wound incision. A summary and comparison of the results are shown in Table II-1 and II-2. Also shown are data obtained from another St. Luke's surgery room that contained a laminar flow system similar to the Experimental System and results from a regular operating room.

Table I-1 Evaluation Data Summary

	Contamination Rate/Wound Culture	Airborne Contamination Bacteria/ liter (cu. ft.)	Infection Rate *	
			Surgically Induced	All Sources
Total Experimental System	4.2%	0.0004 (0.011)	0	4.1% 2.1%
Experimental System, Laminar Flow Only	5.2%	0.0005 (0.014)	0	1.3%
Previous St. Luke's Laminar	4.3%	0.0035 (0.1)	-	4.3%
Regular Operating Room	22.0%	0.1380 (3.9)	-	4.6%

*Not directly comparable, see Section IV.C.3.

II. CONCLUSIONS AND RECOMMENDATIONS

A. DATA EVALUATION

1. Conclusions

a. The use of a laminar flow clean room provides a significant reduction of airborne contamination when compared to a regular operating room. The regular operating room bacteria count in the air at the wound site was 0.1380 bacteria/liter (3.9 per cubic foot). Use of the previous St. Luke's clean room or the experimental system reduces this count to 0.0005 bacteria/liter (0.014 per cubic foot).

b. Wound contamination rates are reduced by the use of a laminar flow clean room, the use of the total (including helmets and gowns) experimental system did not indicate a significant further reduction. The overall wound contamination rate for the total system was 4.2% compared to 4.3-5.2% using the laminar flow clean rooms only and 22.0% for a regular operating room.

c. Definitive conclusions with regard to the reduction of the incidence of wound infections cannot be made at this time. However, to date, the use of the experimental system reflects a zero infection rate traceable to the surgical procedure. The overall infection rate from all sources including post operative for the experimental system was 2.1%. This compares to a 4.6% infection rate for a regular operating room and 4.3% for the previous St. Luke's clean room.

2. Recommendations

Further usage and evaluation of the System should be continued to provide a broader data base and further confirmation of the results. Since surgically-induced infections could occur up to two years later, data collection should be continued for at least another 18 months.

B. SYSTEM DESIGN AND USAGE

1. Conclusions

a. The system, as designed, satisfactorily performed the functions for its intended usage as an experimental system. There have not been any mechanical or electrical failures.

b. For the type of surgery performed during the evaluation period, the System can be used by the surgery team without jeopardizing the surgical procedure.

2. Recommendations

a. Future helmet fabrication should consider alternate methods to reduce the visual distortion in the lower area.

b. Future shoulder pad design should consider additional size adjustment or be provided in a range of sizes to increase stability and reduce fatigue. Improvement could also be made in reducing the forces necessary to install the helmet onto the shoulder pad.

c. For extensive use of the System, a range of gown sizes should be provided.

d. Future design improvements should include wrench flats on the enclosure caster stems.

e. The design of a separate module containing the helmet ventilation system and communications system should be considered to allow the use of the helmets and gowns in existing laminar flow hospital clean rooms.

III. INTRODUCTION

A. PROGRAM DESCRIPTION

This program was performed in a 12-month time span. The objective of this program was to evaluate the effectiveness of an Experimental System in reducing infections induced during a surgical procedure. The purpose of the System was to provide the equipment and procedures to eliminate if possible, the airborne contamination and contamination generated by the surgery personnel.

The System was designed, developed, fabricated and tested by Martin Marietta Corporation. At no cost to the NASA contract, St. Luke's Hospital, Denver, Colorado utilized the System during actual surgery conditions, collected bacteriological data and evaluated the System for effectiveness in reducing infections resulting from the surgical procedure.

To accomplish the objectives of the program, the effort was performed in the following four tasks:

Task 1 - Configuration Selection consisted of conducting preliminary design analysis, layouts, sketches and tradeoffs to define a selected configuration. The results were presented in a design review for approval by the NASA Technical Monitor.

Task 2 - Equipment Specification and Assembly included the preparation of procurement specifications, detail design drawing preparation, hardware procurement, fabrication and assembly. Where possible, the System was fabricated from standard commercial hardware and constructed in accordance with good commercial practices.

Task 3 - Test activities included the preparation of development and acceptance test plans and test procedures. Development tests and preliminary acceptance were performed at Martin Marietta prior to shipment. After delivery and installation at St. Luke's, final acceptance tests were performed. Also under this task, operating and maintenance instructions were prepared.

Task 4 - Experimental Data Collection and Evaluation was primarily performed by St. Luke's. The System was used during actual surgical procedures. Data was collected which included patient information, surgery performed, equipment used, wound cultures, air contamination sampling and infection data. Comparisons were made of bacteriological, air sampling and infection data with the use of the Experimental System, and with the use of a regular operating room.

B. BACKGROUND

In 1895, 39% of all clean surgical wounds became infected.[6] By 1940, most up-to-date hospitals were reporting infection rates of approximately 5%.[7] Riley[8] reviewed the subject of hospital or nosocomial infections and found that the rate of wound infections for all types of surgery was 9.4% in Great Britain in 1960[9] and 7.5% in the United States in 1964.[10] The rate for hip surgery has been reported at 6.4% in the United States[11] and 8% in England.[12] These figures serve only to emphasize that while surgical infection has been reduced significantly, it is still a menace. At St. Luke's Hospital the uncorrected surgical infection rate was 1.3% in 1969. When only major surgery is considered, the rate then rose to about 3%. Further analysis of this local data is not possible, but the rate for initially clean cases involving large exposure of tissues would probably be significantly higher.

With the advent of implant and transplant surgery, the threat of infection looms larger since infection in these procedures often causes at least failure in reaching the operative objective, if not death. During the past 20 years, it has become possible to replace many of the body's joints with mechanical substitutes which function quite effectively in the great majority of cases. It has long been known in orthopedic surgery that infection associated with implantation of a foreign substance usually requires removal of the foreign substance in order to control the infection, and therefore failure of the operation. Recently, complete replacement of the hip with a plastic socket and metal ball has become practicable. These components are held in place within the body with a rapidly self-curing acrylic, polymethylmethacrylate. In no other operation are such large amounts of foreign materials permanently implanted within the body. Their removal prompted by infection is not only difficult, but it leaves the patient with significant disability due to a frail, often painful, false joint. Because the operation requires exposure of relatively large areas of the body's tissues, the possibility of bacterial contamination by either direct contact or airborne routes is increased. Relatively large numbers of these procedures are now being done for severe arthritis with very gratifying results. Failure is almost always associated with infection, which is running about 4% with a high of 9% in the series[1-4] reported to date. The St. Luke's operating team has performed more than 200 of these operations. One patient has experienced a severe, deep wound infection which necessitated three months of hospitalization (compared to the usual three weeks) and which ultimately led to her demise.

Therefore, not only does infection cause pain, suffering and significant disability, but it may also cause death. Furthermore, its very significant economic impact can be readily appreciated in terms of hospital and lost time from work costs. For instance, if a patient required 80 days extra of hospitalization at a daily cost of $80.00, then the additional expense would be $6,400.00.

Considering the above facts and figures, and stimulated by St. Luke's one disastrous experience with infection as well as by the encouraging reduction in the rate of infection achieved by others[1-5] doing total hip replacements, the Experimental System was conceived to reduce the possibility of airborne contamination of surgical wounds.

Three routes of contamination leading to surgical wound infection are recognized.[13] These are:

1. Endogenous - from the patient himself.

2. Contact - from direct innoculation of the wound by hands and instruments, etc.

3. Airborne - deposition or settling of bacteria into the wound from the air.

Of these, contact contamination is the most important and has been combated in many ways utilizing what is now generally classified as sterile technique. Endogenous contamination via the patient's blood stream from remote foci of infection and skin are combated by first eliminating the focus of infection and by careful asceptic skin preparation prior to surgery.

The third route, i.e., the airborne route, has been the subject of considerable interest during recent years. Ford, Peterson and Mitchell[14] studied the number and type of airborne bacteria in operating rooms, using a slit sample and found that the concentration varied from 0.053 to 0.65 organisms per liter per minute (1.5 to 18.3 per cubic foot per minute). Others[16] have confirmed these findings. The concentration of organisms varied directly with the number and activity of people in the operating theater. The predominant types of organisms encountered include Staphlococcus and Epidermidis bacillus sp. Both of these organisms are known to be pathogenic occasionally. Furthermore, the incidence of Staphlococcus aureaus was low but always present. Burke[15] has demonstrated that a significant number of pathogenic bacteria recovered from surgical wounds originate from non-scrubbed operating room personnel. Coriell, Blakemore and McGanity[16] have documented that man is a prolific

source of particulate matter in the air. This material of human origin is composed of shed epithelial scales and bacteria from the skin and formites from the upper respiratory tract expelled into the air during speech and explosive breathing. They demonstrated that the concentration of airborne bacteria at the wound site is twice that in the remainder of the room because of the intense concentrated activity of the surgeons and scrub nurses. These studies were conducted in modern well-ventilated and air conditioned operating theaters.

Others[17,18] have shown that human shedding contributed the major fraction of bacteria in the air of operating rooms and most of these organisms reach the air either through inefficient facial masking[19] or through the pores in conventional operating attire[20-22]. Bacteria-laden exfoliated skin from the temple and forehead is free to sluff off and contaminate the incision. The present surgical masks (respiratory tract) vary in bacteria collecting efficiency between 15 to 99.7%. For example, the Ford, Peterson and Mitchell[19] study shows the Johnson and Johnson gauze mask to average 15.6% efficient, the 3-M Dacron 39.6%, and the C. R. Brand Fiberglass 99.7%. However, the efficiency rates decrease with time and accumulated moisture.

The High Efficiency Particulate Air (HEPA) filter was first developed from atomic research[23] and has subsequently been used in the construction of clean rooms for spacecraft component assembly.[24] Using these filters with a blower system, it has been possible to reduce significantly the particulate matter and bacteria in air within confined spaces fed by the blower filter system. In fact, the air's bacterial count is reduced from ten to one hundred times and the particulate count to less than 10,000 particles sized greater than 0.3 micron using Class 100 filters.[25-28] Others[29-33] have shown the applicability of the clean room to surgical uses.

These findings have been more recently confirmed by Coriell, Blakemore and McGarrity[16] using a vertical airflow system and by Fox and Maitland[34] using a horizontal or crossflow system.

Coriell, et al,[16] found that bacterial counts in an unairconditioned 1927 operating room varied between 0.1 to 1.0 colonies per liter (3 to 28 colonies per cubic foot) while those in a new modern air-conditioned operating room varied between 0.07-0.21 colonies per liter (2-6 colonies per cubic foot). Counts always rose with increased activity and when the operating room (OR) door was opened. Counts were found to be twice as high in the immediate vicinity of the wound compared to more remote areas of the OR. Using the clean room, counts were uniformly zero with no activity and average 0.014

per liter (0.4 per cubic foot) at the wound. Furthermore, particulate matter in the air averaged 7064 per liter (200,000 per cubic foot) in the new air conditioned regular OR and 38.85 (1,100) in the laminar flow clean operating room. These investigators concluded that the system could be expected to produce air with less than 353 (10,000) particles and 0.014 (0.4) bacteria per liter per minute using a 5.8 meter (19-foot) per minute flow rate.

Fox and Maitland[34] and Fox[35] have used a horizontal system in an enclosure measuring 6.1 x 4.6 x 2.5 meters (20' x 15' x 8'3"). The air velocity was 24.3 meters (80 feet) per minute giving an air change rate in the enclosure of 240 times per hour. In their system, using both a simulated and a real operating environment, bacterial counts from numerous sampling sites within the module averaged 0.001 organisms per liter (0.03 per cubic foot) per minute. All instruments on the back tables remained sterile for at least 90 minutes in the module as opposed to a 30% contamination rate in a normal operating room.

Visits to the Beatan Memorial Hospital in Albuquerque, New Mexico and the Hollywood Presbyterian Hospital have been made to view existing laminar flow surgical rooms. The New Mexico facility has been in existance for several years and it was the opinion of Dr. John Whitcomb that it has been very effective in reducing the rate of infection to about 0.5%. The California facility had been in use for only a few months, but no infections had occurred in 116 consecutive total hip replacement procedures compared to 2 in 32 procedures prior to use of the module. In addition, two members of St. Luke's staff visited Wigan, England, to evaluate the facilities at the Center for Hip Surgery where the rate of infection has been reduced from 8% to 0.5%.[12]

Charnley[12] and Bechtol[36] are using modified helmets to protect against nasopharyngeal contamination and facial shedding. No recent publications on this subject have been found. As noted earlier, Fode et al[19] found that the great majority of surgical masks were ineffective bacterial filters and Walter[37] has documented this clinically.

The foregoing material indicates that infection in clean surgical wounds continues to occur and that the risk of infection in implantation procedures is particularly alarming. Therefore, any procedure or procedures which could produce reduction in clinical wound infection should be considered seriously.

IV. SYSTEM DESIGN

A. DESIGN GUIDELINES

Certain guidelines were used in the system design to ensure the applicability to the intended use. These guidelines were to provide a system that:

1. Could be installed in an existing surgery room with a minimum of facility modifications.

2. Is portable within the surgery complex with a minimum of disassembly and reassembly.

3. Can be stored within the surgery room in a floor space envelope of approximately 1.22 x 3.05 meters (4 x 10 feet).

4. Can be easily cleaned and maintained.

5. Is compatible with all major surgical operations.

6. Is safe for operation in a surgery room environment.

7. Makes maximum use of existing surgery room lighting.

B. SYSTEM DESCRIPTION

The system design is depicted by SK203613000 drawing package previously transmitted to NASA. Briefly, the final as delivered configuration is as described below:

1. Portable Clean Room - The portable clean room consists of a Class 100 horizontal laminar flow system per Federal Standard 209a and a transparent wall and ceiling enclosure (see Figure IV-1).

a. Laminar Flow Filter System - The laminar flow filter system consists of a bank of high efficiency particulate air (HEPA) Class 100 (3.5 liter) filters and associated prefilters and blowers. The unit, in conjunction with the walled enclosure and other operating room equipment, provides the capability of delivering and maintaining an air cleanliness level per Federal Standard No. 209a Class 10,000 (350 liter). Air flow is horizontal with a nominal velocity through the laminar cross section of 27.45 meters per minute (90 feet per minute) with a uniformity of plus or minus 6.10 meters per minute (20 feet per minute)

Figure IV-1 Assembled Portable Clean Room

throughout the undisturbed enclosed area. The laminar cross section is nominally 3.05 meters (10 feet) wide with a height compatible with the enclosure. The HEPA filters remove all particulate larger than 0.3 micron with an efficiency of 99.97 percent.

The filter system was provided by Envirco Division of Becton, Dickinson and Company of Alburquerque, New Mexico. The unique feature of this system is the modular design for portability. The filter system blowers are mounted in two blower towers that attach to each end of the plenum with quick release devices (see Figure IV-2). Each blower tower contains two 1 horsepower motor/blowers. Each blower tower is 0.6 x 0.9 x 1.7 meters (2 x 3 x 5-1/2 ft), weighs 130 Kg (350 lb) and is caster mounted. The blower towers may be disconnected and rolled to an outside area for servicing. Prefilters are installed at the air intakes for removing gross particulate.

The filter plenum which is caster mounted is only 0.4 meters (15 inches) deep and is divided into two 1.5 meter (5 ft) wide sections that latch together. Each section with filters installed weighs approximately 112 Kg (300 lb). Protective perforated aluminum screens are provided for the face of the HEPA filters.

b. Enclosure - The enclosure is constructed of an anodized aluminum framework and plexiglass panels. The enclosure was fabricated by the Pittsburg Plate Glass facility at Denver, Colorado.

When the sliding doors are extended, a 3.05 x 3.05 meter (10 x 10 feet) work area is provided inside the enclosure with a ceiling height of 2.6 meters (8 feet 5 inches). The transparent walls and ceiling allows the use of the existing facility lighting and provides slots in the ceiling for the existing surgical lights (see Figure IV-3). The end opposite the laminar flow filter system is open.

The enclosure is mounted on casters to provide portability within the surgery room. For storage within the surgery room, the enclosure ceiling and walls may be collapsed and folded toward the face of the filter modules and the blower towers located inside (see Figure IV-4). In this stored configuration a floor space of approximately 1.5 x 3.4 meters (5 x 11 feet) is utilized (see Figure IV-5). In addition, the capability is provided for dismantling the entire assembly for transfer to another surgery room.

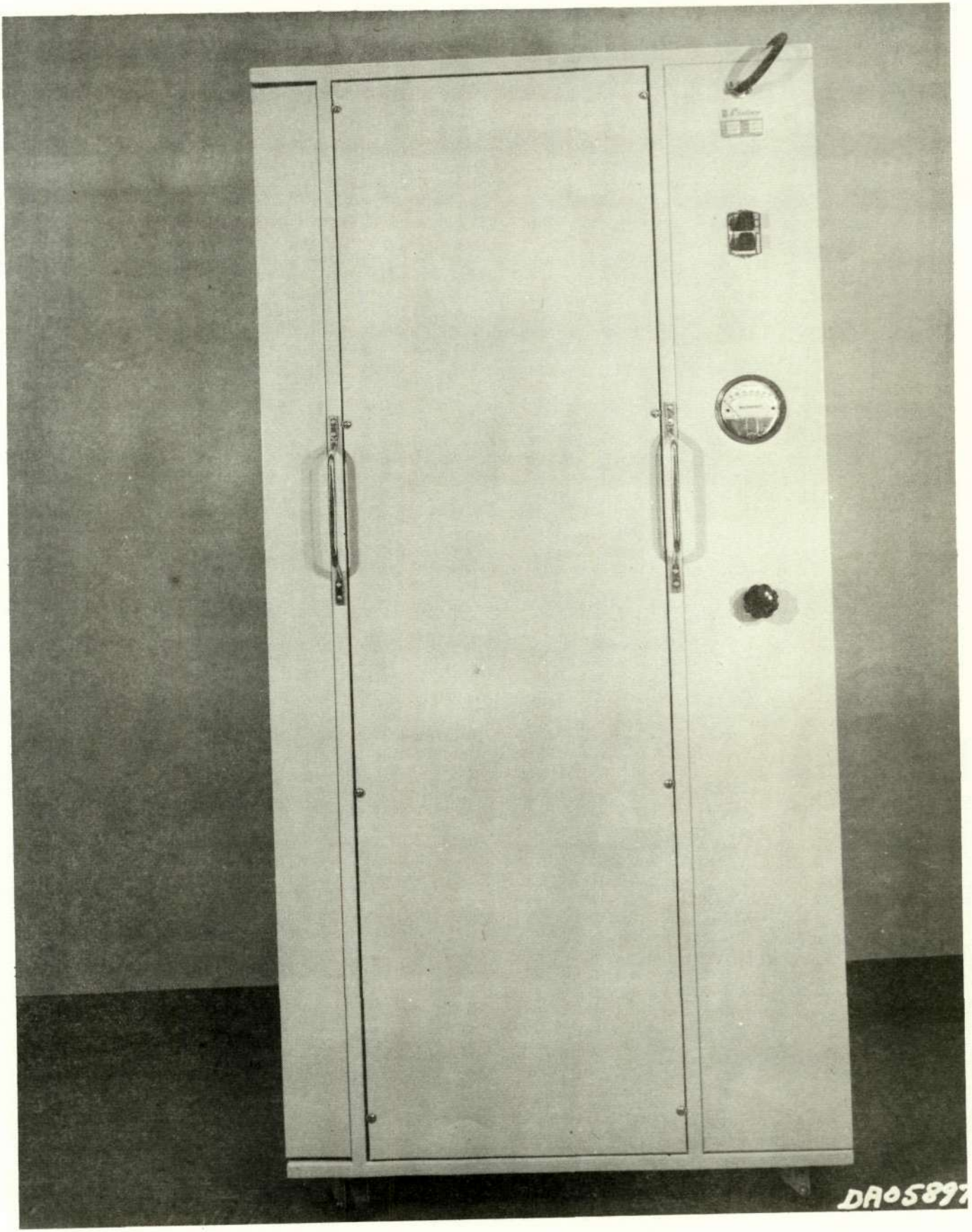

Figure IV-2 Filter Blower Tower

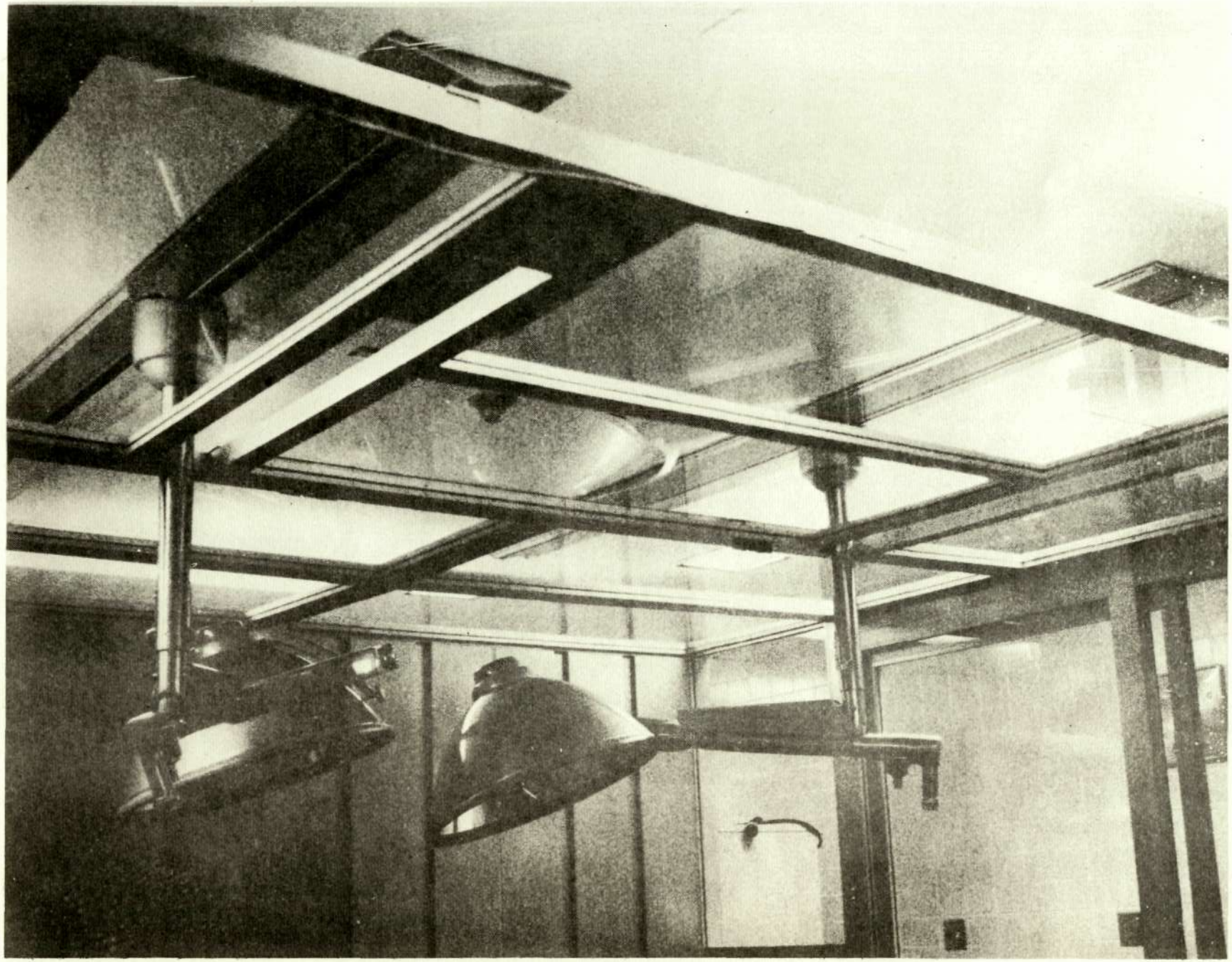

Figure IV-3 Overhead Surgery Light Provisions

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Figure IV-5 Collapsed Portable Clean Room

The enclosure hinged panels are latched together with fasteners as shown in Figure IV-6. A T-handle allen wrench tool is provided with the system for actuating the fasteners. When completely assembled, the ceiling and walls are self-supporting. Panel joints are sealed by sponge rubber gaskets and/or overlap plates.

2. Helmet Assembly

Six full bubble transparent helmets which attach to shoulder pad-harness assemblies are provided for members of the surgery team. The helmets are made of clear plexiglass and are approximately 33 cm (13 inches) in diameter and 32 cm (12.5 inches) high. The helmet flange mates with a clip at the rear of the shoulder pad and a quick release latch on the front. Sealing is accomplished by a hollow round PVC gasket. The helmet may be rotated to any position with respect to the shoulder pad. A 2.5 cm (1 inch) hole at the top provides a ventilation inlet. Additional ventilation flows from the gown to the shoulder pad outlet providing body cooling.

The shoulder pad is constructed of molded Kydex (Trademark of Rohm and Hass), an acrylic-polyvinyl chloride alloy. The helmets and Kydex shoulder pad were manufactured by Plasticrafts, Inc., of Denver, Colorado. The pad is formed to rest on the shoulders with a foam rubber cushion and provides an adjustable brace on the back. An adjustable 5.1 cm (2 inch) nylon webbing strap with elastic sections attachs to the back brack and snaps to an adjustable 2.5 cm (1 inch) vertical strap at the front (see Figure IV-7, IV-8 and IV-9).

At the rear of the shoulder pad are connections for the ventilation and communications umbilical. Inside the shoulder pad a connector is provided for attachment of the headset.

The headsets are made by Pacific Plantronics of Santa Clara, California. The headset consists of an adjustable head band, a choice of six sizes of ear plugs, boom microphone and amplifier/receiver unit. If the person wears glasses, the amplifier/receiver unit may be attached to the frames of the glasses in lieu of the head band.

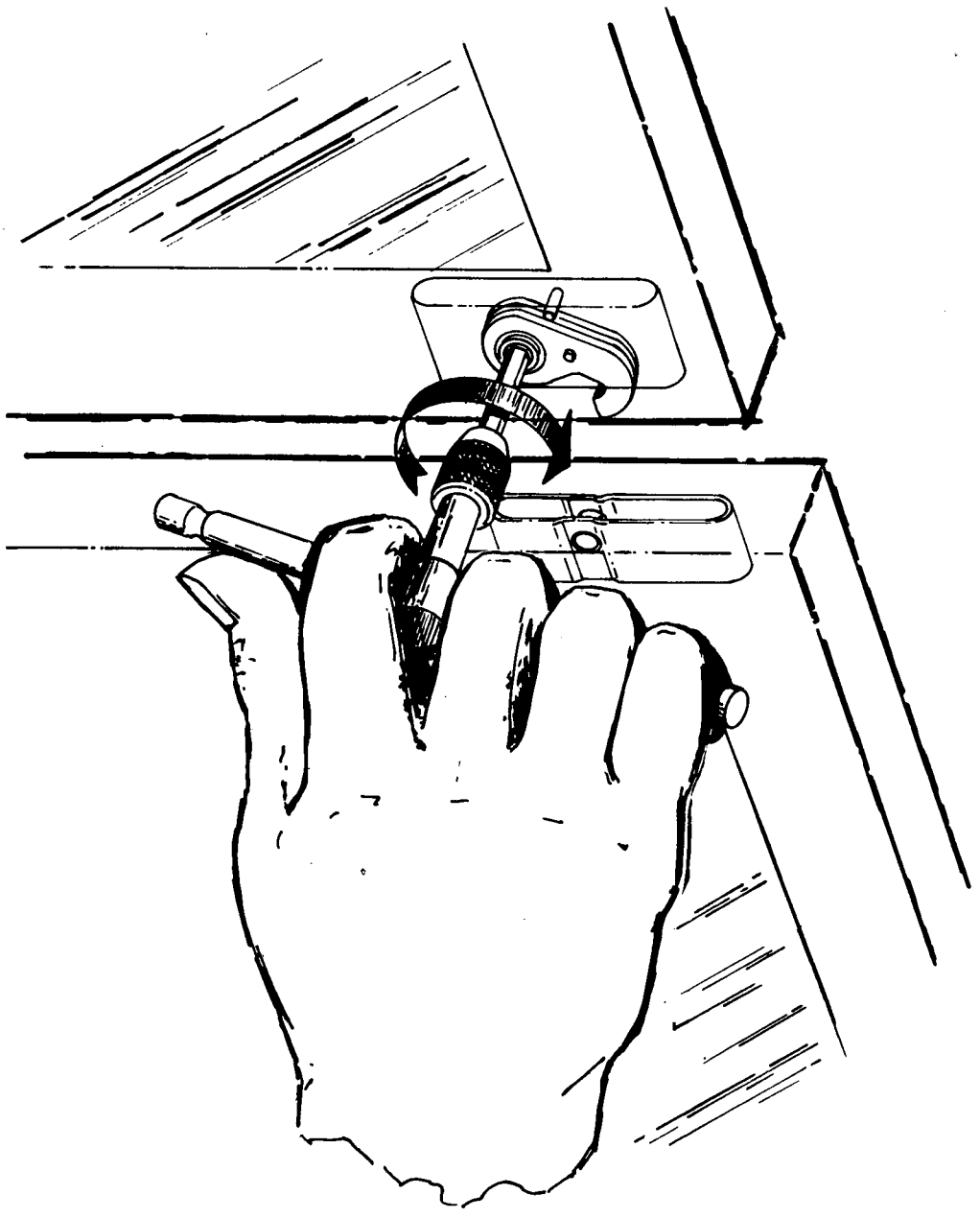


Figure IV-6 Enclosure Panel Fastening

Figure IV-7 Shoulder Pad Donning, Front

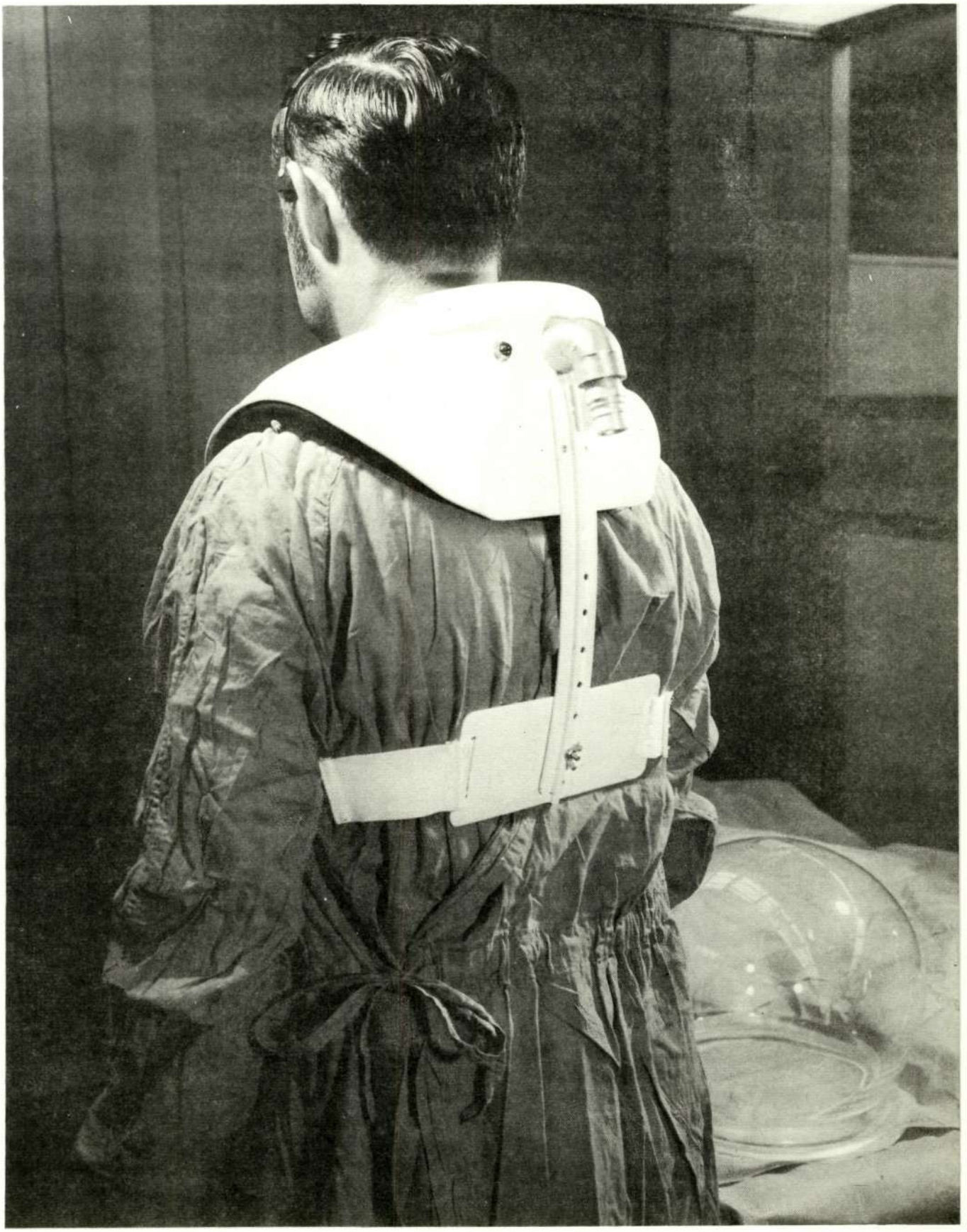


Figure IV-8 Shoulder Pad Donning, Rear

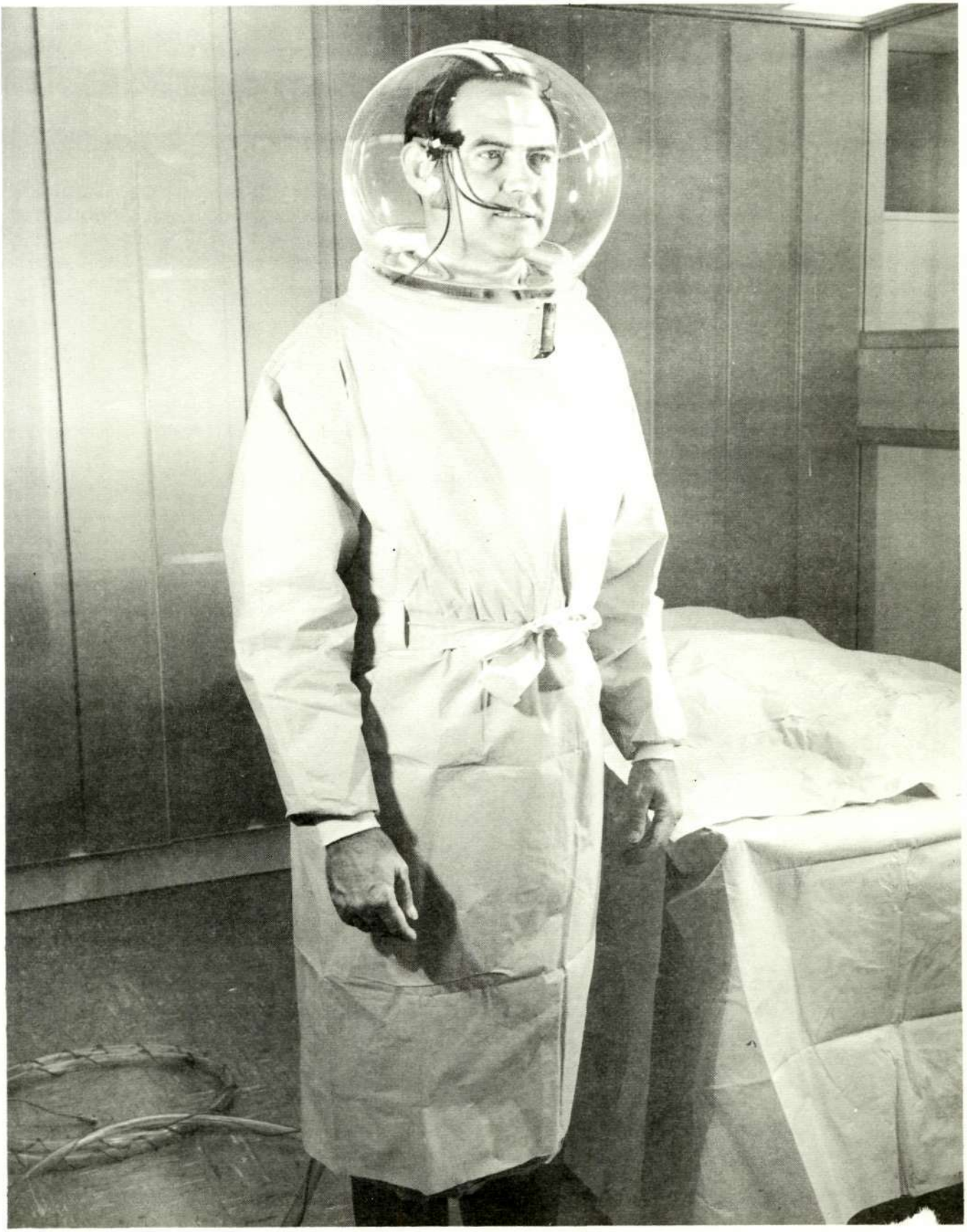


Figure IV-9 Helmet and Gown Donning

3. Helmet Ventilation System

The helmets are ventilated by a vacuum system that pulls air through the helmet, out an umbilical at the rear of the shoulder pad and discharges into the main filter bank plenum. The ventilation system is provided with two vacuum blowers for redundancy (see Figure IV-10). In case one blower fails, the other will supply a six-man team with a minimum air supply of 113 liters per minute (4.0 CFM). Normally, the ventilation system will supply 170-350 liters per minute (6.0-12.3 CFM) to each helmet depending upon the number of helmets in use. The air flow to each helmet can be individually regulated by valves at control panels located outside the enclosure.

The vacuum blowers are integral blower/motor units made by Rotron Manufacturing Company, Woodstock, New York. The blowers are mounted in the filter plenums. The performance output of each blower for the system application and pressure drop is approximately 708 liters per minute (25 CFM) at 506 newton meter^2 (22.5 inches of water).

The ventilation system plumbing is of PVC pipe, fittings and valves. The valves are removable for maintenance. The plumbing is routed through the enclosure framework between the blowers located in the filter plenum, the control panels and the helmet umbilical connections located at the bottom of the inside enclosure walls.

The umbilicals are of flexible PVC tubing with a 1.6 cm (5/8 inch) I.D. Snaptite straight through quick disconnects are provided on each end for mating to the shoulder pad and wall connections.

4. Communications

The communications system provides a microphone/earphone headset for each helmet assembly. A microphone is provided on the outside of the enclosure at the control panel for a circulating nurse. Another microphone is provided at the end of the enclosure for the anaesthetist or he may use an auxiliary communications cable and headset. A speaker is provided on both the inside and outside wall of the enclosure (see Figure IV-11). Volume controls are provided for each individual microphone, earphone and speaker on the main control panel located outside the enclosure (see Figure IV-12).

A Bogen Model CHS35 amplifier (35 watt) and two Bogen Model MX6A-6 four-channel mixers were modified to mount inside the control panel. The communications cabling is routed through the enclosure framework and connectors are provided at enclosure disassembly joints. The communications umbilical is wrapped around the ventilation umbilical and is provided with quick disconnects on each end.

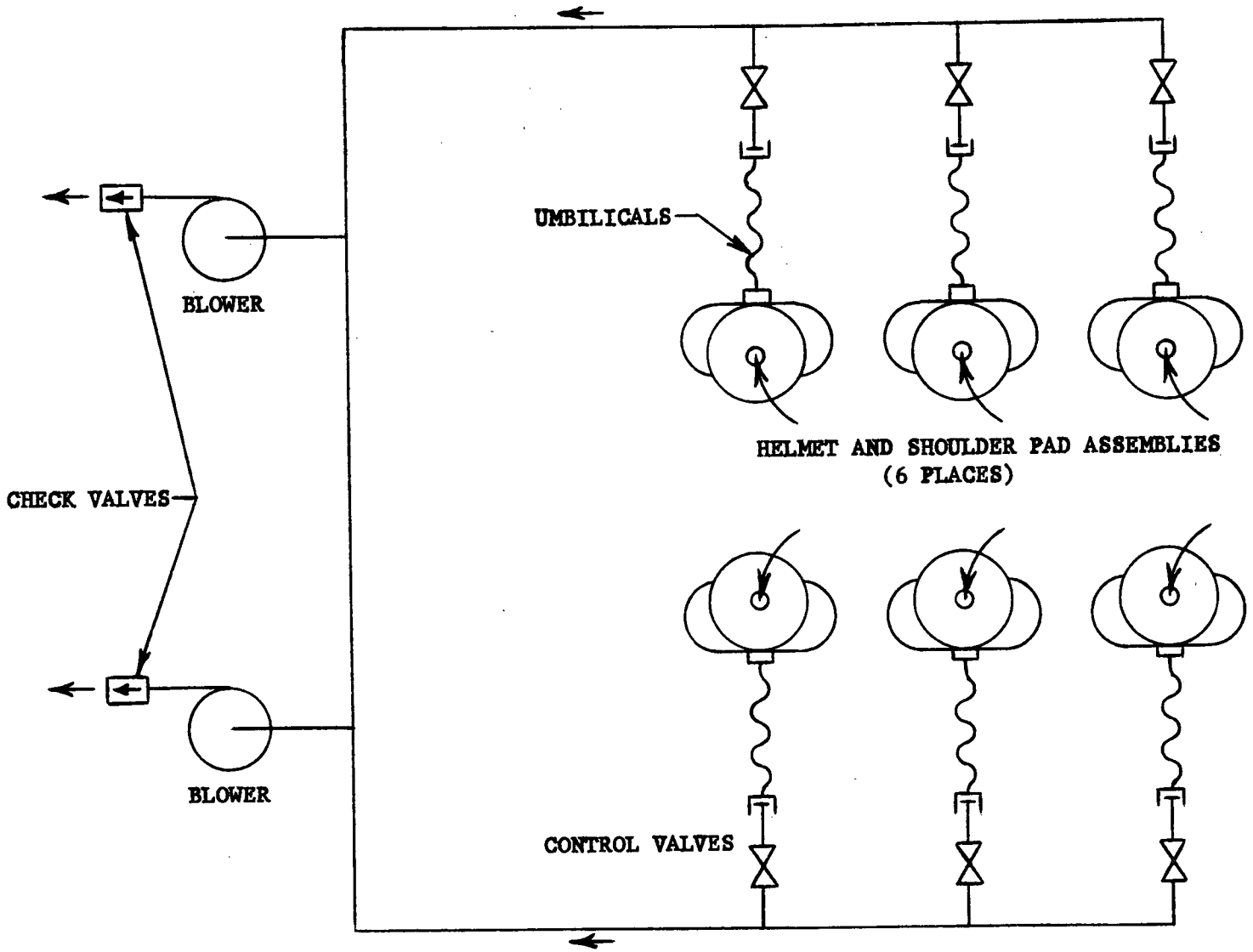


Figure IV-10 Helmet Ventilation System Schematic

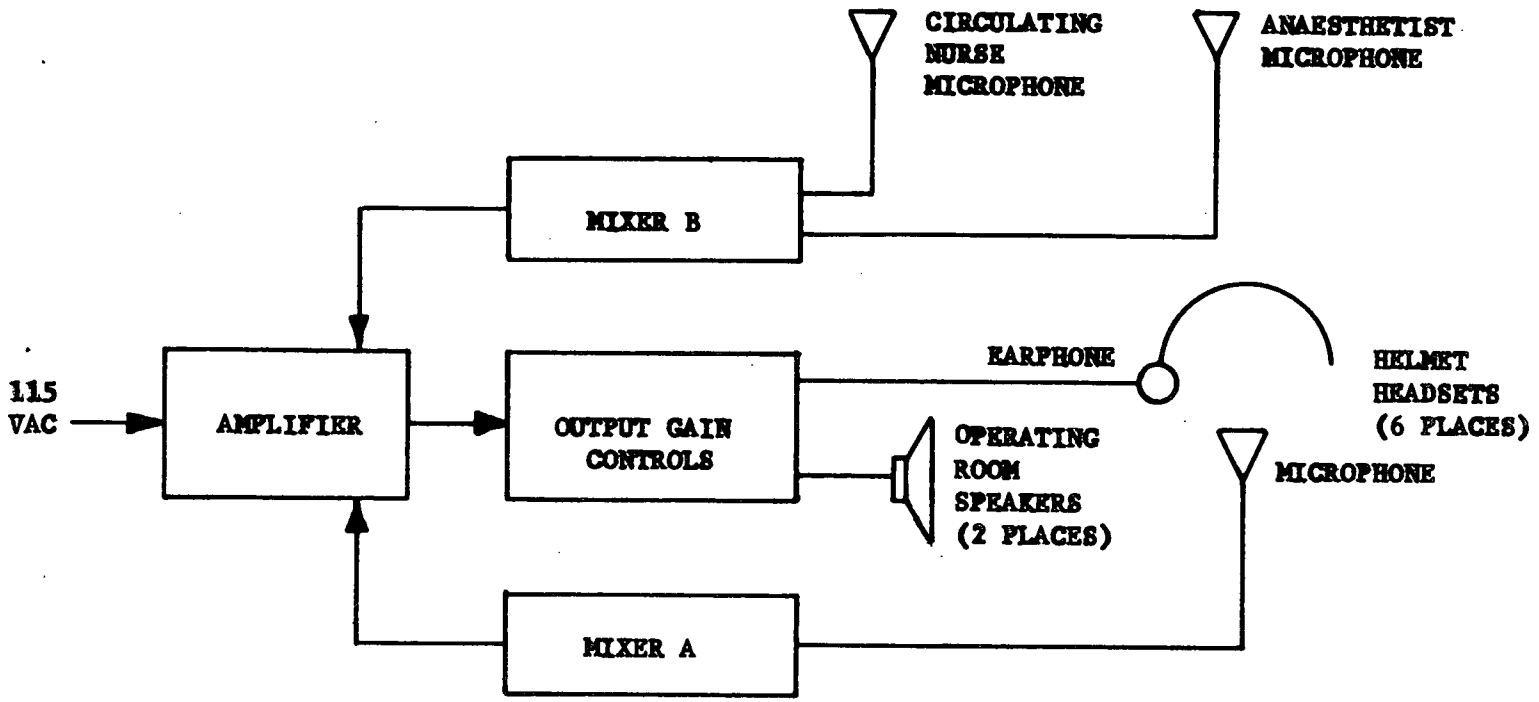


Figure IV-11 Communications System Schematic

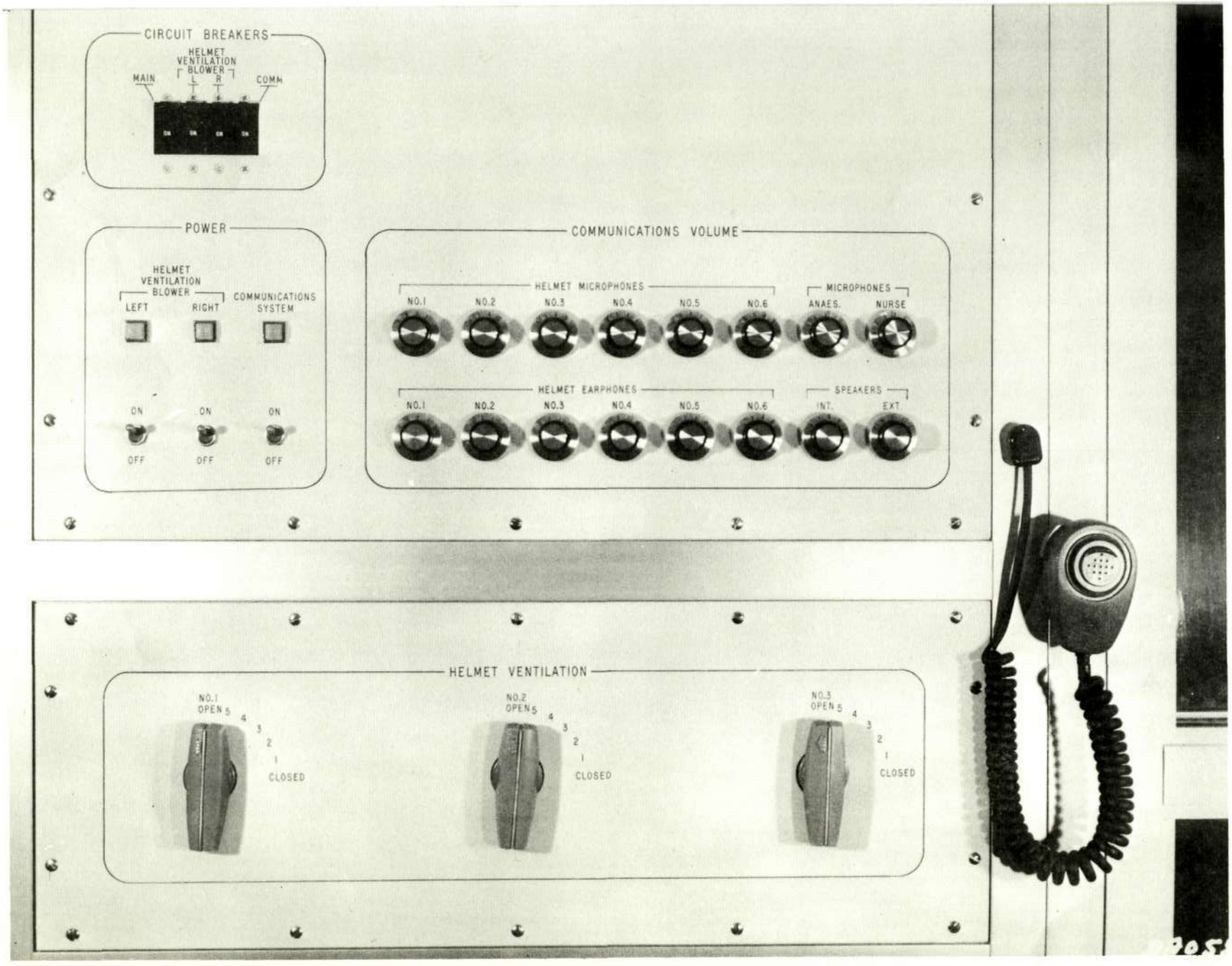


Figure IV-12 Control Panel

5. Gowns

The gowns are provided by Johnson and Johnson Surgical Specialty Division at no cost to the contract. The gowns are a disposable split-back type that fastens around the shoulder pad below the helmet neck ring (see Figure IV-9). The gown may be fastened above or below the umbilical connections at the rear. The gowns extend below the knee level and have full, cuffed sleeves. The gowns are prefolded such that only internal surfaces are touched during donning except for the snaps at the rear of the neck.

The gown material is of a patented laminated gauze, cellulose and resin construction that is liquid repellant with low linting and static electricity characteristics. Previous tests by others have demonstrated that this material is an effective obstacle to bacteria contamination. Tests indicate that even when wet, the material prevents bacteria migration for at least six hours.

6. Electrical System

The electrical system is designed to meet the Class 1, Division 1, Group C electrical requirements as specified by the National Electric Code. Each filter blower tower module has explosion proof wiring and motors and uses 208 volt single phase power.

The helmet ventilation and communications system utilizes 115 VAC. The 115 VAC subsystem is non-explosion proof, however, in accordance with the Code, is located above the 1.3 meter (5 foot) level. Each subcircuit is operated by a toogle switch and protected by circuit breakers (see Figure IV-12).

7. Noise

The system was designed for minimum noise generation. As a design goal, the sound level measured at any point in the surgery room at 0.9 meters to 1.8 meters (36 to 72 inches) above the floor was not to exceed 65 decibals average within the octave bands centered at 500, 1000 and 2000 cycles per second.

8. Construction and Workmanship

The system was fabricated from standard commercial parts and materials where practical. Workmanship was in accordance with good commercial practices and company standards.

V. DEVELOPMENT AND ACCEPTANCE TESTS

A. DEVELOPMENT TESTS

Development tests were performed at Martin Marietta prior to shipment to St. Lukes. The tests were performed in a room that simulated the St. lukes surgery room size and volume. The tests were performed in accordance with the D203613-002 Development Test Plan and D203613-006 Development Test Procedures. Results were reported in D203613-007 Development Test Report. The tests performed and results were as follows:

1. Assembly, Collapsability, Portability and Storage Test

The objective of this test was to evaluate the physical design of the portable clean room. The test was to demonstrate the assembly, collapsing and storing in place, portability within a surgery room, and disassembly and transfer of the portable clean room.

The results of this test are noted on Figure V-1 Data Sheet. Starting from the fully assembled condition (see Figure IV-1), the system was collapsed to the storage configuration by two personnel in six minutes. The system was raised on the casters and relocated in six minutes (see Figure IV-4).

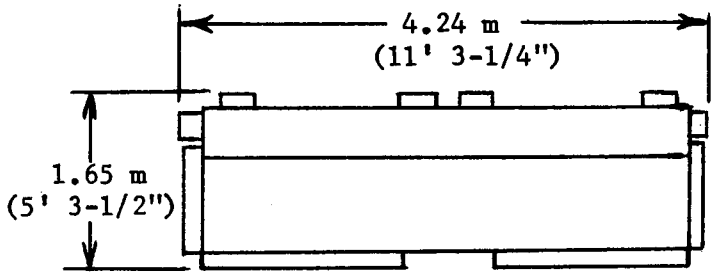
Two personnel disassembled and assembled the system except for de-erecting and erecting the filter modules which requires four personnel. Due to the test facility ceiling height, the filter modules could not be physically erected or de-erected during this test. However, after delivery to St. Luke's, this portion of the test was performed and the time required included in the figures shown (see Figure V-2). Complete disassembly was accomplished in 47 minutes. Complete reassembly was done in 78-1/2 minutes.

The overall envelope dimensions in the storage mode are shown in Figure V-1. Ceiling height erection dimensions also reflect removal of the rear filter module casters and ceiling overlap plate if required for clearance. Hallway and door clearances for transfer were verified.

One problem was noted in adjusting the caster height. Due to the weight in the assembled (or collapsed) condition, the casters are difficult to adjust. This difficulty is easily overcome by using a block and short lever bar. For any future build, wrench flats should be provided on the caster stems.

Figure V-1 Data Sheet - Assembly, Collapsability, Portability & Storage Test

Task	Elapsed Time (min)	No. of Personnel	Remarks
Collapsability	6.0 min	2	
Portability	6.0 min	2	
Disassembly	47 min	4-2	4 personnel for erection-de-erection, all other 2 personnel
Assembly	78-1/2 min	4-2	



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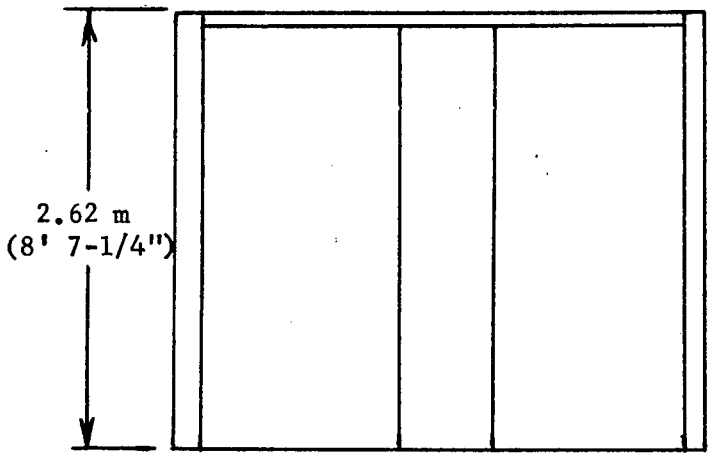


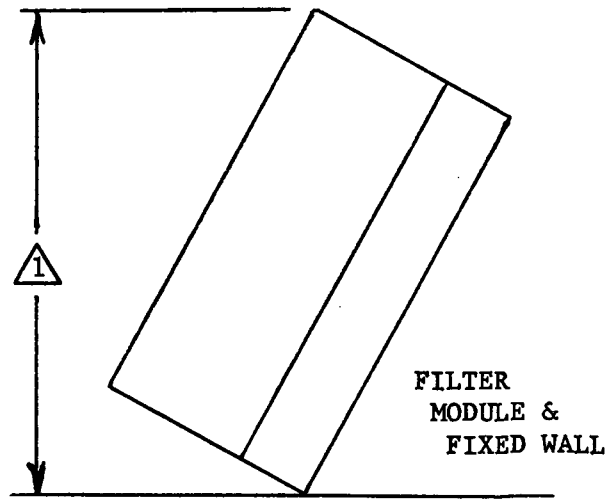
ELEVATION

STORAGE DIMENSIONS

(1) 2.85 m (9' 6-3/4")

2.84 m (9' 5-3/4") without casters

2.82 m (9' 5") without casters and ceiling overlap plate



ERECTION DIMENSION

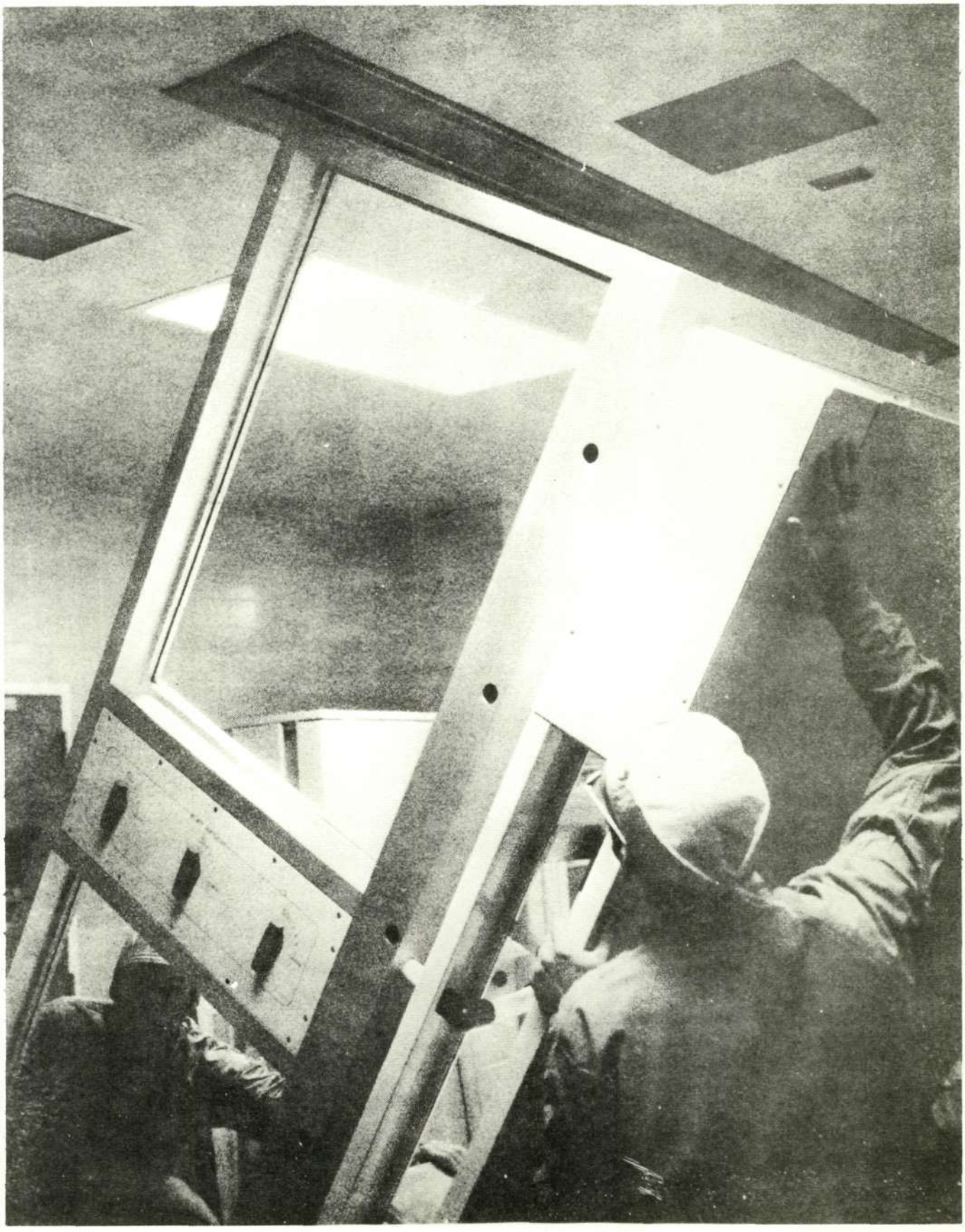


Figure V-2 Filter Module Erection at St. Luke's

2. Rate of Laminar Flow Test

The ability of the filter banks to maintain a laminar flow velocity profile in the enclosure was to be assessed during this test. For the purpose of this test, laminar flow was defined as that air flow in which the entire body of air within a confined area moves with uniform velocity along parallel flow lines. Federal Standard 209a requires a rate of laminar flow of 27.45 meters (90 ft) per minute plus or minus 6.10 meters (20 ft) per minute measured across the entire cross-sectional area. With the system assembled in a simulated surgery room, the main filter blowers and ventilation blowers were operated. Air velocity measurements were taken at selected locations throughout the portable clean room enclosure. It was necessary to adjust the filter blowers to attain the required air velocity value of 27.45 plus or minus 6.10 meters per minute. The air velocity measurements and locations are shown on Table V-1. The data indicates an expected profile. At the undisturbed filter end of the enclosure the air velocities meet Federal Standard 209a requirements. Toward the ceiling the velocities increase along the walls as the air moves around the ends of the sliding doors to return to the blowers. Near the floor adjacent to the walls, the velocity decreases due to the air escaping under the sliding doors. The velocity immediately upstream of the ceiling slots is high and downstream low due to the air exiting through the slots. At the end of the enclosure the velocities are low in the center due to the air mass hitting the blank wall of the simulated surgery room creating a back pressure.

3. Static Pressure Test

The objective of this test was to measure the pressure differential, if any, existing between the portable clean room enclosure and a simulated operating room. The purpose was to assist in determining the direction of air leakage and the need for sealing the enclosure ceiling light slots. Attempts to measure the pressure differential were unsuccessful in that the values were less than the readout capability of the manometer available (0.2 inches of water increments). The cross-sectional area available outside the enclosure for the air flow return to the blowers was observed to be approximately the same as the enclosure, therefore, the differential pressure should be near zero. The decision was made to abandon this test and rely upon the following smoke tests to determine air leakage flow direction.

Table V-1 Data Sheet - Rate of Laminar Flow Test

Location	Rate of Flow m/min					
	From Left Side			From Right Side		
	0.3/m	0.7/m	1.2/m	1.2/m	0.7/m	0.3/m
0.6 meters (2 ft) downstream of filter						
0.3 meters (1 ft) above floor	31.39	26.51	22.86	23.17	27.08	27.74
0.9 meters (3 ft) above floor	32.61	23.17	23.47	23.17	22.25	25.29
1.8 meters (6 ft) above floor	32.61	23.17	22.56	21.95	22.25	31.70
2.4 meters (8 ft) above floor	30.78	26.51	26.83	23.47	24.08	26.51
1.5 meters (5 ft) downstream of filter						
0.3 meters (1 ft) above floor	31.39	26.21	22.56	21.34	23.47	30.48
0.9 meters (3 ft) above floor	27.74	24.38	24.08	23.78	22.56	25.90
1.8 meters (6 ft) above floor	32.61	22.86	26.51	25.90	22.86	28.65
2.4 meters (8 ft) above floor	31.70	27.43	35.65	33.22	27.43	33.53
3 meters (10 ft) downstream of filter						
0.3 meters (1 ft) above floor	18.29	27.43	15.24	15.85	24.38	24.38
0.9 meters (3 ft) above floor	24.08	22.56	11.58	11.88	25.90	26.21
1.8 meters (6 ft) above floor	27.74	23.47	9.14	9.14	24.38	30.17
2.4 meters (8 ft) above floor	35.97	30.48	20.73	21.34	28.34	36.58

4. Air Flow Pattern Test

The objective of this test was to evaluate the laminar air flow patterns within the enclosure when occupied by a simulated operating team and equipment. The system was operated and the enclosure occupied with test subjects representing a surgery team. The surgery room operating table and overhead ceiling lights were simulated. A single point source stream of smoke was released immediately upstream of the object under consideration. The fog stream was positioned at several locations such that the stream impinged upon obstructions such as the personnel, table and ceiling lights. The stream was evaluated for possible detrimental flow patterns that may cause contamination to migrate to a patient surgery wound area. Smoke tests were performed as described above and the following observations were made:

a. Around large objects such as the table and surgery lights, the smoke stream maintained a distance of approximately 20 cm (8 inches) from the object (see Figures V-3 and V-4).

b. From a point near the table surface, the smoke would rise, slightly turbulent. See Figure V-4.

c. Around a person's body the smoke would become turbulent with an excursion of approximately 15 cm (6 inches).

d. From a point approximately 30 cm (1 foot) above the surface of the table and in line with the front of a person standing at the side of the table, the smoke went behind the person.

e. Around small objects such as an arm, the smoke excursion was approximately 8 cm (3 inches).

f. From any point between the ceiling and approximately 30 cm (1 foot) down and upstream of the ceiling slots, the smoke rises and exits through the ceiling slots.

g. Below table top level, the smoke would travel parallel to the floor.

h. Air exits the enclosure around the sliding glass doors, under the sliding glass doors and around the edge of the ceiling.

i. No air leakage was observed in or out of the enclosure at the wall and ceiling joints.

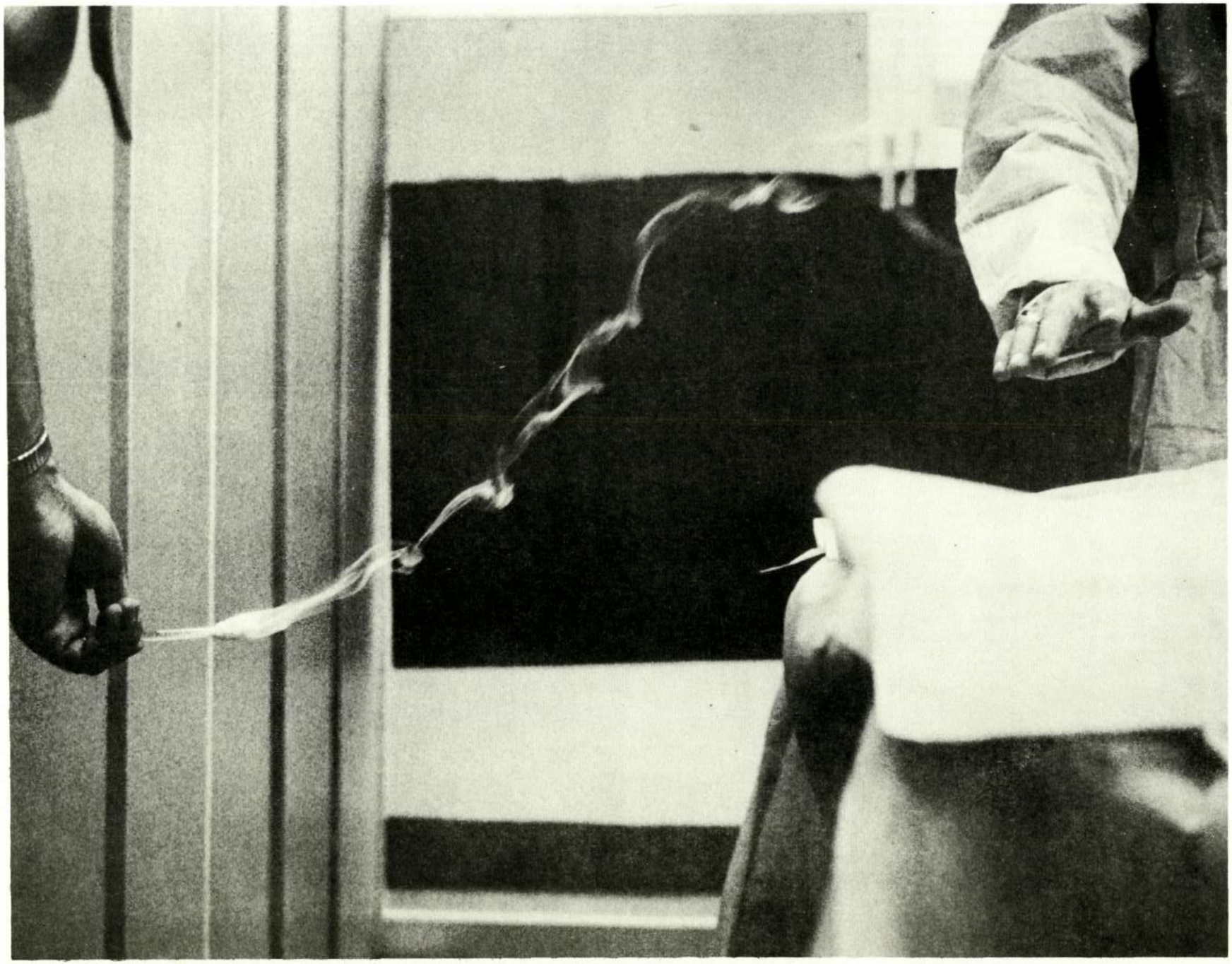
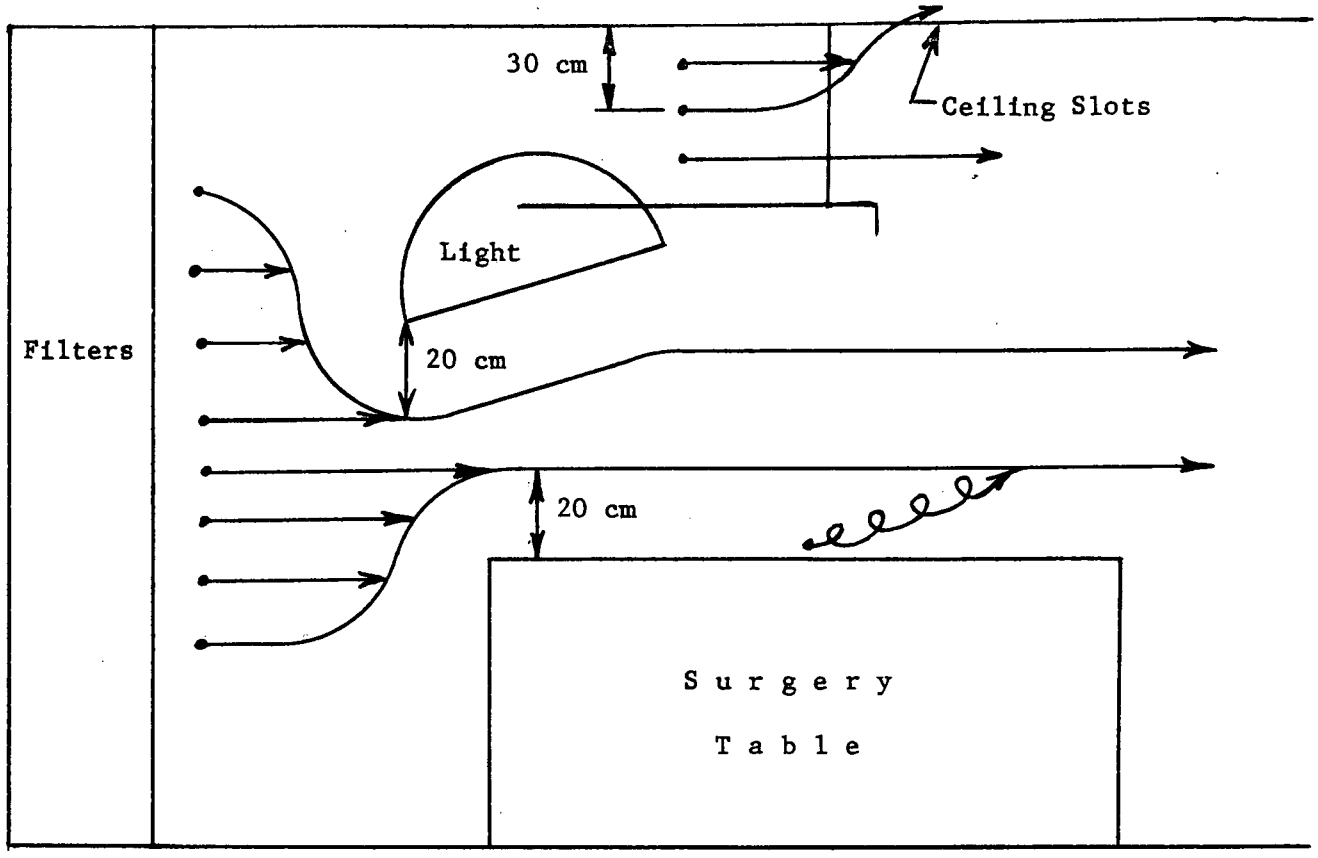
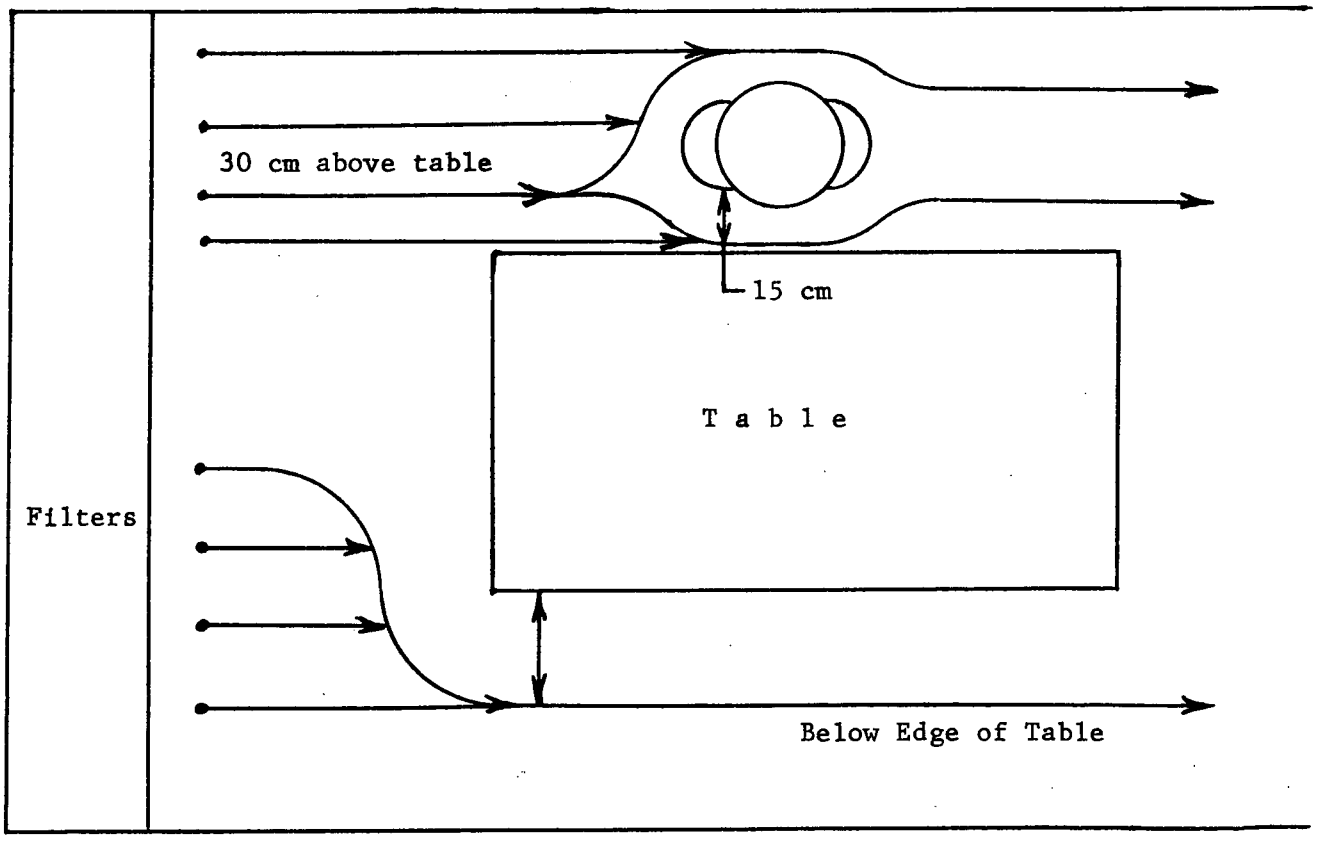


Figure V-3 Smoke Pattern Over Table

Figure V-4 Smoke Patterns Around Objects



ELEVATION



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It was concluded at the end of the test that there were not any air patterns that might be detrimental to a surgery operation. It is recommended that the following precautions be taken and included in the operating procedures:

a. Personnel should always stand at the side of the patient and avoid standing upstream of the table.

b. Equipment should not be placed in front of the filter face or upstream of the patient.

c. Passing of instruments across the table should be done 30 cm (1 foot) or more above or downstream of the wound incision.

It was also concluded that it is unnecessary to seal the ceiling slots.

5. Electrostatic Buildup Test

The objective is to evaluate the electrostatic buildup on the plexiglass walls of the enclosure. The portable clean room was completely assembled in a simulated surgery room. The main filter blowers were operated for a continuous three hours. At the completion of the three hours, the electrostatic potential readings were taken at each of the plexiglass panels on the walls and ceiling of the enclosure and of the air within the enclosure. All readings taken at each panel with a Sweeney Model SEW-1125 were within the green band of $\pm$ 3 volts. Readings varied both positive and negative even on the same surface of a panel. Readings taken with a Sweeney Model SWE-1128 15 cm (6 inches) away from the panels varied within a range of $\pm$ 1.3 kv with two exceptions. The inside surfaces of the upper left and lower right hinged wall panels both indicated spots registering a positive 3.3 kv.

The high readings were of concern for equipment usage in a hospital environment. It was felt that the high readings could be attributed to the fact that the test facility had an ungrounded floor and system had been assembled and used for several weeks without any cleaning of panels.

After installation in St. Luke's, the exterior surfaces of the system were thoroughly cleaned with antiseptic solutions. Approximately 48 hours later during the laminar flow certification tests and after the system had been operating for three hours, Model SWE-1128 readings were again taken. All readings registered zero.

6. Noise Level Test

The objective of this test was to measure the noise level within the enclosure. The portable clean room was completely assembled in a simulated surgery room. The main filter blowers and ventilation blowers were all in operation. The sound was measured by a No. 2203 Bruel & Kjaer sound level meter which has an accuracy within the 20-30,000 cycle range of ± 1 db. Sound level readings were taken in several locations within the enclosure and also at the control panel on the outside. "A" scale, 500, 100 and 2000 cycle readings were taken at an elevation of approximately 1.2 meters (4 feet). The design goal was for a maximum of 65 db average at 500, 1000 and 2000 cycles.

The sound level readings and locations are shown in Table V-2. "A" scale readings were 70-71 within the enclosure and 64 at the control panel. 500, 1000 and 2000 cycle readings ranged from 57 db to 70 db within the enclosure and 48-61 db at the control panel. All readings are considered acceptable for the intended usage of the system.

7. Ventilation System Test

The objective of this test was to evaluate the ability of the ventilation system to deliver an adequate flow of air to the surgery team. The major results of the ventilation system tests are shown on Figure V-5 and Table V-3. The mass flowmeter used for the helmet umbilical measurements had been calibrated just prior to the tests to read in standard liters per minute. Therefore, all flowrate values are for standard conditions of 1 atmosphere, 70°F, dry air. Results are as follows:

a. With the system in full operation and test subjects suited in helmets and gowns, a matrix of measurements of air flow through each helmet umbilical was taken with one to six personnel using the ventilation system. The ventilation system control valves were in the full open position for each helmet in use. This established the maximum flowrate capability to each helmet with varying number of helmets being serviced. With both blowers in operation, the umbilical flowrates ranged from a single helmet only maximum of 357 L/min (12.6 CFM) to 212 L/min (7.5 CFM) minimum with all six helmets on line and all valves in the open position. The design value minimum of 226 L/min (8 CFM) with all helmets on line was attained by adjusting Helmet No. 1 and No. 6 valves to the 5 position with all other valves full open. (NOTE: The flowrate band shown on Figure V-5 results from the difference in flowrates helmet to helmet due to the differences in subcircuit pressure drops).

Table V-2 Data Sheet - Noise Level Test Results

Location & Type of Reading	Sound Level Reading, db		
	0.3 m (1 ft) From Left Wall	Center	0.3 m (1 ft) From Right Wall
0.6 m (2 ft) downstream of filter			
"A" scale	71	70	71
500 cycle	69	69	68
1000 cycle	65	65	66
2000 cycle	62	57	60
1.5 m (5 ft) downstream of filter			
"A" scale	71	71	70
500 cycle	70	69	68
1000 cycle	66	67	66
2000 cycle	62	58	57
3 m (10 ft) downstream of filter			
"A" scale	70	70	70
500 cycle	68	69	67
1000 cycle	66	66	65
2000 cycle	60	58	57
Control Panel			
"A" scale		64	
500 cycle		61	
1000 cycle		56	
2000 cycle		48	

Note: All readings approximately 1.2 meters (4 ft) above floor.

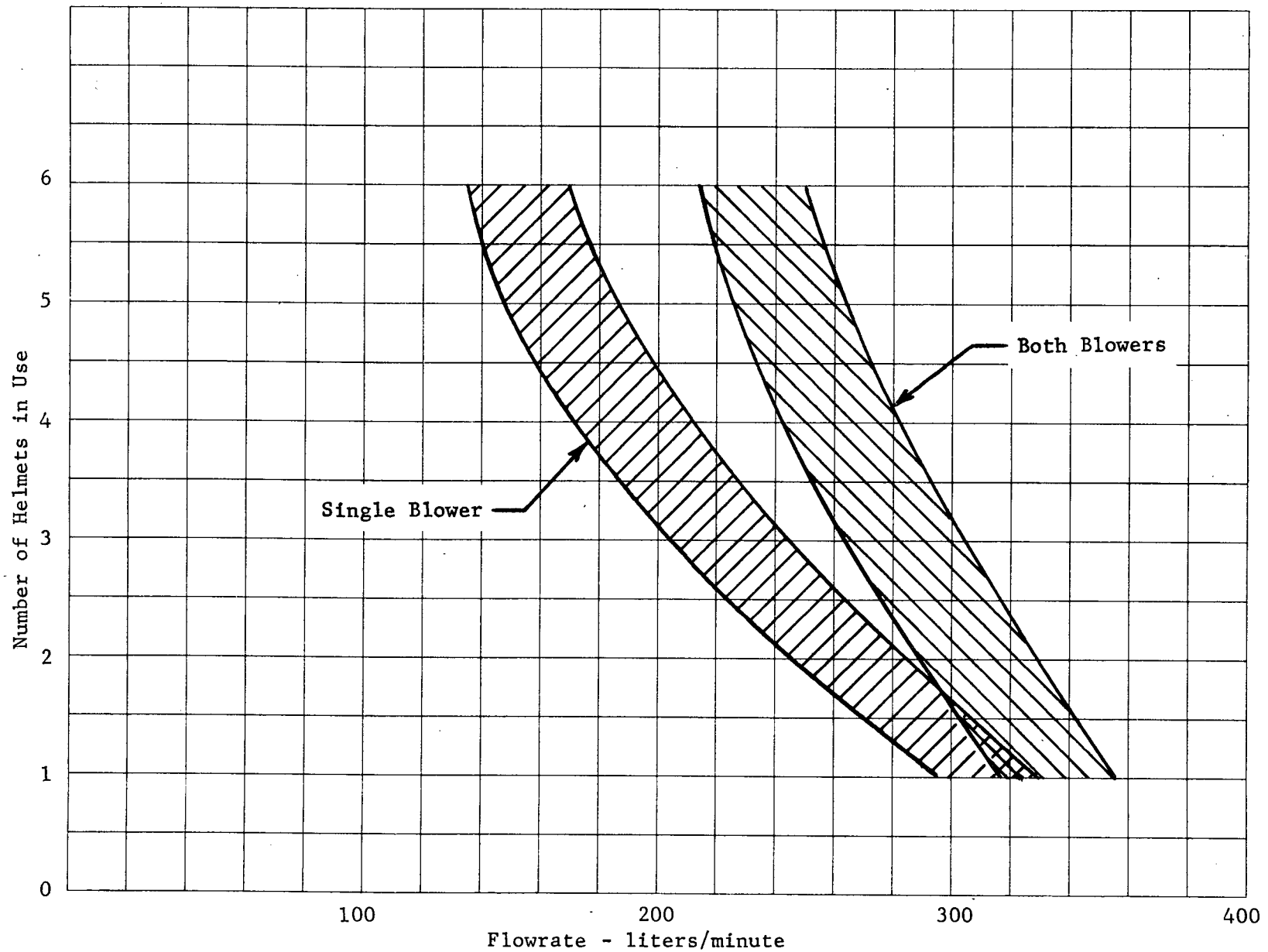

Figure V-5 Helmet Ventilation Flowrates

Table V-3 Gown Ventilation Test Results

Test Condition	Umbilical Flow-rate L/min	Top of Helmet Flow-rate L/min	Flowrate Differ-ence L/min	Gown Temp °K	Room Temp °K	% PCO_2
Test Subject 1						
Unmodified Shoulder Pad						
Prior to Jogging	293	38	255	303.67	300.90	0.4
After Jogging				304.79	300.90	1.2
Modified Shoulder Pad	293	43	250	302.84	300.90	0.3
Prior to Jogging	293	43	250	302.84	300.90	0.3
After Jogging	(No Perspiration Noted)			304.23	301.45	1.0
Test Subject 2						
Unmodified Shoulder Pad						
Prior to Jogging	293	120	173	304.23	300.90	0.4
After Jogging				304.23	300.90	1.2
Modified Shoulder Pad						
Prior to Jogging	293	71	222	302.57	300.90	0.4
After Jogging	(Damp Forehead)			302.84	300.90	1.1

b. With the left ventilation blower off, measurements were taken for one to six helmets on-line (see Figure V-5). This was repeated with the left blower on and right blower off. This established the minimum flowrate capability to each helmet in the contingency mode of a ventilation blower failure. In this contingency mode of one blower inoperative, the lowest flowrate recorded with all helmets on line was 135 L/min (4.8 CFM). This is above the required minimum of 113 L/min (4.0 CFM).

c. For the test subject in the above test that had the lowest flowrate, the condition was duplicated and the PCO_2 percentage was measured. For the low flowrate of 135 L/min, the PCO_2 level in the helmet was recorded as 1.1%. This was approximated from a reading range of 0.6-1.7% noted due to the breath to breath cycling of the meter. This was greater than the desired maximum of 0.75%, however, for all normal flowrates of 170 L/min (6.0 CFM) and above, the PCO_2 was measured at 0.4% or less.

d. Two test subjects were used to evaluate the effect of ventilation through the top of the helmet and through the gown. The umbilical flowrate was established at 293 L/min which was the average flowrate with three helmets on line (the normal number of the surgery team helmeted for the operations to be performed during the evaluation period). The air flow entering the top of the helmet was measured. The difference between the umbilical and top of helmet flowrates determined the amount of ventilation under the shoulder pad and through the gown. The PCO_2 inside the helmet and temperature inside the gown was measured (see Table V-3).

   The first test subject was physically small and the shoulder pad fit was relatively loose. The difference in flowrate was 255 L/min with 38 L/min entering the top of the helmet. The PCO_2 was 0.4% and the inside gown temperature was 303.67°K (88°F).

e. The above test subjects were then asked to jog in place for five minutes. Temperature and PCO_2 were measured and signs of perspiration noted. The gown temperature increased to 548.67°K (89°F) for the first test subject and 304.23°K (88°F) for the second. PCO_2 increased to 1.2% for both subjects. After jogging, the second test subject had a damp forehead. Otherwise no signs of head or body perspiration on either subject was noted.

f. Tests d and e above were repeated with the same test subjects using a shoulder pad that had been modified to provide an opening between the shoulder pad and the torso area. For the first test subject, the flowrate difference did not improve due to the shoulder pad fit. For the second test subject, the flowrate difference increased to 222 L/min. In both cases, in the standing position, the gown temperature decreased 0.83°K (1.5°F) and 1.66°K (3.0°F) respectively. After jogging, the temperature improvement was 0.56°K (1°F) and 1.39°K (2.5°F).

g. With only No. 1 helmet on-line, the umbilical flowrates for each of the valve positions 1-6 noted on the control panel were measured. This was repeated with all helmets on-line and measuring flowrates at the same No. 1 helmet umbilical for the valve positions. From this, the approximate percentage of flow for each valve position can be determined if a setting other than full open is desired. Approximate percentage of full flow for each valve position was determined to be: open - 100%, 5 - 95%, 4 - 84%, 3 - 40%, 2 - 10%, 1 - 0%, and closed.

8. Human Factors Evaluation

The objective of this test was to evaluate the helmet, shoulder pad, harness, communications, and gowns from a human factors viewpoint with respect to comfort, fit, ease of donning and doffing, and operational usage. Six test subjects were asked to don helmets, shoulder pads, headsets and gowns. The system was fully operated. The test subject commented on the human factors considerations. In addition, the communications volume controls were adjusted to determine "normal" settings. Three subjects simulated an emergency mode of having to remove helmets in the event of ventilation or communication failure. The six test subjects were chosen to provide a range from small to large physical size. The human factors comments are summarized in Table V-4.

For the smaller personnel, a loose mate of the shoulder to the shoulder pad was noted; however, when properly strapped down with the harness, the stability and mobility was not affected. For the large subject, tightness in the shoulder of the gown was noted.

Straight ahead visibility through the helmet was good although some distortion was noted in the lower portion where the material is thicker. The helmets could be readily removed in the simulated emergency. Some difficulty was encountered in installing the helmet ring under the clip at the rear of the shoulder pad, although with practice, it could be accomplished without undue strain.

FOLDOUT FRAME 1

FOLDOUT FRAME 2

Table V-4 Human Factors Evaluation

CONSIDERATION	C O M M E N T					
Test Subject	1 (MT)	2 (MWB)	3 (MB)	4 (RC)	5 (RS)	6 (GP)
Chest Size	44	38	39	38	40	52
Shoulder Pad & Harness						
Donning	No problem	No problem	No problem	No problem	No problem	Tilted glasses
Fit	Good	Good	Loose mate of pad	Loose mate of pad	Good	Snug fit
Comfort	Good	Good	Good	Good	Good	Good
Doffing	No problem	No problem	No problem	No problem	No problem	Some manipulation req'd to clear head
Helmet						
Donning	No problem	No problem	Difficult to insert in ring clip	Difficult to insert in ring clip	No problem	Difficult to insert ring clip
Fit	Good	Good	Good	Good	Good	Head close to top
Comfort	Good	Good	Good	Good	Good	Good
Visibility	No problem	Distortion in lower area noted	Good	Distortion in lower area noted	Good	Good
Doffing	No problem	No problem	Some tightness removing from ring clip	Some tightness removing from ring clip	Good	No problem
Emergency Doffing	Easily accompl.	-	Easily accompl.	-	-	Easily accompl.
Gown						
Donning	No problem	No problem	No problem	No problem	No problem	Tight pull to snap
Fit	Good	Some looseness	Some looseness	Some looseness	Good	Tight in shoulder area
Comfort	Good	Good	Good	Good	Good	Good
Mobility of Subject	Good	Good	Good	Good	Good	Good
Communications						
Headset Comfort	Good	Good, used glasses	Good	Good	Good	Good, used glasses
Earphone Setting	5.0	5.0	4.0	4.5	5.0	5.0
Microphone Setting	3.0	3.0	2.5	2.5	3.0	3.0
Ventilation Flow	Good, no problem breathing	Good	Noticed flow on top of head	Good	Good	Noticed flow on top of head
Noise	Helmet voice noise not objectionable	Helmet voice & ventilation noise noted, became adjusted	Not objectionable	Not objectionable	Not objectionable	Helmet voice & ventilation noise noted, not objectionable

The ventilation flow through the top of the helmet was not objectionable. The noise of the air flow exit at the rear of the shoulder pad was noticeable but not excessive since all normal sounds outside the helmet cannot be heard.

The most notable effect of wearing the helmets was the inside sound when the person spoke. The sound is trapped in the helmet and at first seemed loud. Once the person was aware of the effect and became accustomed to it, the noise was not as noticeable or considered objectionable. Previous experiments had been performed using padded earphones and/or foam padding in the rear of the helmets without a significant noise reduction. In each case proper fit and mate of the gown to the shoulder pad was verified. Except for the tightness in the shoulders of the largest subject previously noted, the gowns did not restrict movements. With subjects completely attired, mobility to each end of the table with umbilicals attached was verified.

The communications system volume controls were adjusted for each test subject. The "normal" settings established to be included in the operating procedure were: helmet microphones - 3, helmet earphones - 5, outside microphones - 5, and outside speakers - 3.

9. Electrical Subsystem Tests

The objective of this test was to measure the operating amperages of the electrical subsystems under normal operating loads and to determine the ground leakage current if any. The filter blowers, ventilation system blowers and communications system were activated. Ventilation umbilicals and headsets were connected to all helmet locations. The operating voltages, amperages and ground leakage for each subsystem were measured and recorded.

The operating voltages and amperages are shown in Table V-5. In all cases ground leakage was not detected on a 0-1 milliammeter scale.

10. Material Compatibility Test

The objective of this test was to evaluate the compatibility of materials used in the system with sterilization and cleaning procedures used by St. Luke's Hospital.

Each of the type of materials used on the shoulder pad, harness, umbilical, helmet and enclosure that could be affected were subjected to antiseptic cleaning fluids and/or sterilization procedures that might be used by St. Luke's. Any detrimental effects were noted.

Table V-5 Subsystem Operating Voltages and Amperages

Subsystem	Volts	Amps
Left Filter Blower	207.5	8.7
Right Filter Blower	207.5	8.7
Left Ventilation Blower (TB-1)	112.5	2.4
Right Ventilation Blower (TB-1)	112.5	2.4
Communications (TB-1)	112.5	198 MA
Mixer A (TB-2)	112.5	10.2 MA
Mixer B (TB-2)	112.5	10.2 MA
Amplifier (TB-2)	112.5	178 MA
115 Volt Connector	112.5	198 MA

a. Samples of Kydex (shoulder pad), Armaflex (gasket), PVC hose (umbilical), PVC fitting (valves and plumbing) and plexiglass (helmet and walls) were swabbed daily, five days a week for one month with Dicrobe only.

b. Additional samples, following the same procedure, were cleaned with Dicrobe followed by a distilled water rinse and a 70% isopropyl alcohol rinse.

c. Samples of plexiglass and PVC hose were cleaned with Dicrobe only once a week for one month.

d. Harness webbing and latch hardware were subjected to steam and gas sterilization at St. Luke's Hospital.

After one month application of the cleaning fluid procedures noted, none of the materials showed any signs of detrimental effects. Steam sterilization caused corrosion of the harness hardware. Gas sterilization did not affect the harness or hardware.

For the operating procedures, the Dicrobe solution only was recommended for all surfaces except the plexiglass and harness. Even though detrimental effects were not noted in this test, the cleaning procedures for the helmets reflected the three solution rinse at the recommendation of the Dicrobe manufacturer. The harness was gas sterilized.

11. Conclusions and Recommendations

As a result of the development tests performed, the following conclusions and recommendations were made:

a. Conclusions

1. The system as designed would perform the functions required for its intended use.

2. The portable clean room can be assembled, collapsed, relocated, disassembled, and transferred by two personnel except for filter module erection and de-erection which requires four personnel in reasonable time periods.

3. Laminar air flow velocities meet Federal Standard 209a and air flow patterns were not detrimental to surgery usage. Enclosure ceiling slots did not require sealing.

4. Electrostatic buildup on the plexiglass panels of the enclosure does not occur in the hospital environment.

5. The sound level within the enclosure was acceptable.

6. Helmet umbilical flowrates provide adequate ventilation to surgery team members and PCO_2 levels were acceptable.

7. From a human factors standpoint, the shoulder pad, helmet and gown were acceptable and the surgery team can adequately communicate when fully attired.

8. The materials used in the system were compatible with hospital sterilization and cleaning procedures.

b. Recommendations

1. Future design improvements should include wrench flats on the enclosure caster stems.

2. Improvement could be made in reducing the forces necessary to install the helmet ring under the rear shoulder pad clip.

3. Future helmet fabrication should consider alternate methods to reduce the distortion in the lower area.

4. If, during usage, the surgery team members desire additional ventilation through the gowns, the shoulder pads could be modified by removing a portion of the gasket.

B. ACCEPTANCE TESTS

Preliminary acceptance tests were performed at Martin Marietta prior to shipment and final acceptance tests performed at St. Luke's. The acceptance tests were performed in accordance with D203613-002 Acceptance Test Plan and D203613-005 Acceptance Test Procedures. The preliminary acceptance tests were performed at Martin Marietta on 14 October 1971. The system was disassembled, cleaned, packed and shipped on 15 October 1971. The system was then assembled and installed in the St. Luke's surgery room on 16 October 1971. Final acceptance tests were performed on 18 October 1971. The acceptance tests which were witnessed by the NASA delegated AFPRO representative consisted of the following:

1. Visual Inspection

A visual inspection was performed to verify conformation to design requirements in terms of the following:

a. Configuration

b. Workmanship

The inspection verified:

a. The overall system configuration was in compliance with the Configuration Description Document D203613-001 and as depicted by SK203613000 drawings.

b. The workmanship of the finished product was acceptable in accordance with standard commercial construction practices for similar hardware.

2. Portable Clean Room Assembly Demonstration Test

The capability of portability, assembly and disassembly of the portable clean room consisting of the filter modules, blower modules, and enclosure sections was demonstrated. The envelope dimensions of the major subassemblies, St. Luke's facility drawings, and the D203613-004 Operating Procedures were reviewed to demonstrate the capability of disassembly, transfer and reassembly of the System from one surgery room to another. Using the Operating Procedures, the portable clean room was relocated from a stored configuration and assembled into an operational configuration. This verified that the storage, portability and assembly capability could be performed in accordance with the operating procedures with the personnel and tools specified. Figure V-6 shows the portable clean room in the stored configuration in Operating Room #2 at St. Luke's.

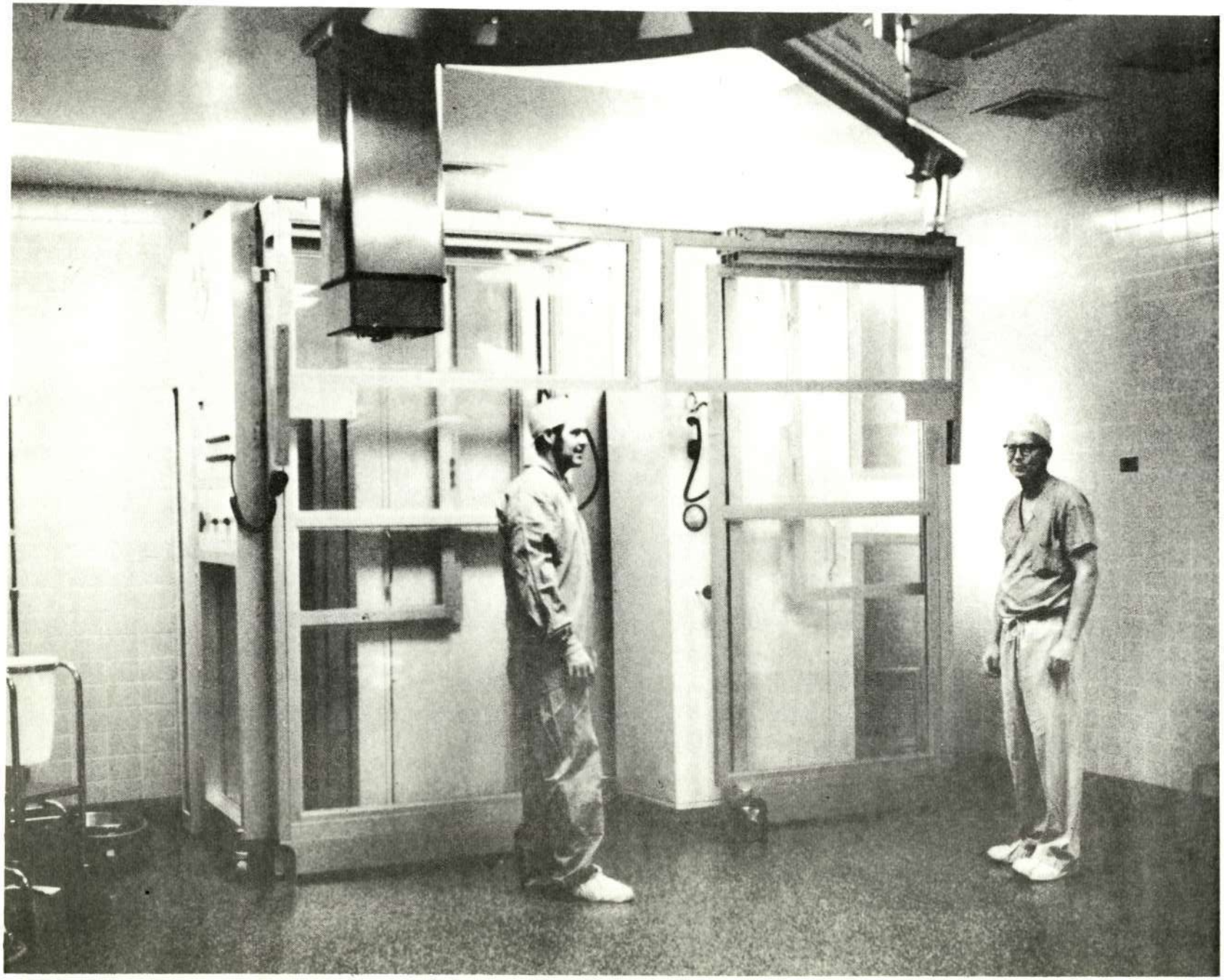

Figure V-6 System Stored in St. Luke's Operating Room

3. Laminar Air Flow and Cleanliness Test (not applicable to Martin Marietta Tests)

The System was tested to verify that the filter/blower assembly delivers air in accordance with Federal Standard 209a, Class 100. This test was performed by the Envirco (filter system manufacturer) representative. The test was performed utilizing the vendor representative procedures and equipment and consisted of the following:

a. The filter/blower subsystem and enclosure were assembled and the filter blowers activated.

b. In accordance with Federal Standard 209a, a high concentration smoke or fog was introduced into the filter bank plenum and the entire downstream surface of the filter installation scanned with an aerosol photometer probe to determine filter integrity and verify no pinhole leaks. No leakage in excess of an aerosol photometer reading equivalent to 0.01 percent of the upstream smoke concentration was allowed.

c. The air velocity through the entire cross section of the airflow was measured. Air velocities through the cross section of the air flow were within 27.45 meters (90 feet) per minute with a uniformity within plus or minus 6.10 meters (20 feet) per minute.

Verification of the above leakage, velocity and uniformity confirmed that the air particle count would not exceed a maximum of 3.5 particles per liter (100 per cubic foot) 0.5 micron and larger. A certification of conformance to Federal Standard 209a was obtained from the vendor representative.

4. Helmet Ventilation System Test

A review of the development test data was performed to verify the capability of the helmet ventilation system providing an adequate supply of air for the surgeons and nurses. A nominal air flow of 170 liters per minute (6 CFM) per helmet and a minimum air flow of 113 liters per minute (4 CFM) per helmet in the contingency mode (one ventilation blower shut down) was verified.

5. Functional Demonstration Test

A functional demonstration test was performed simulating surgery operating conditions to verify the intended use of the System. Utilizing the Operating Procedures, the System was fully activated with personnel attired in helmets and gowns. A mock surgery operation was simulated (see Figures V-7 and V-8).

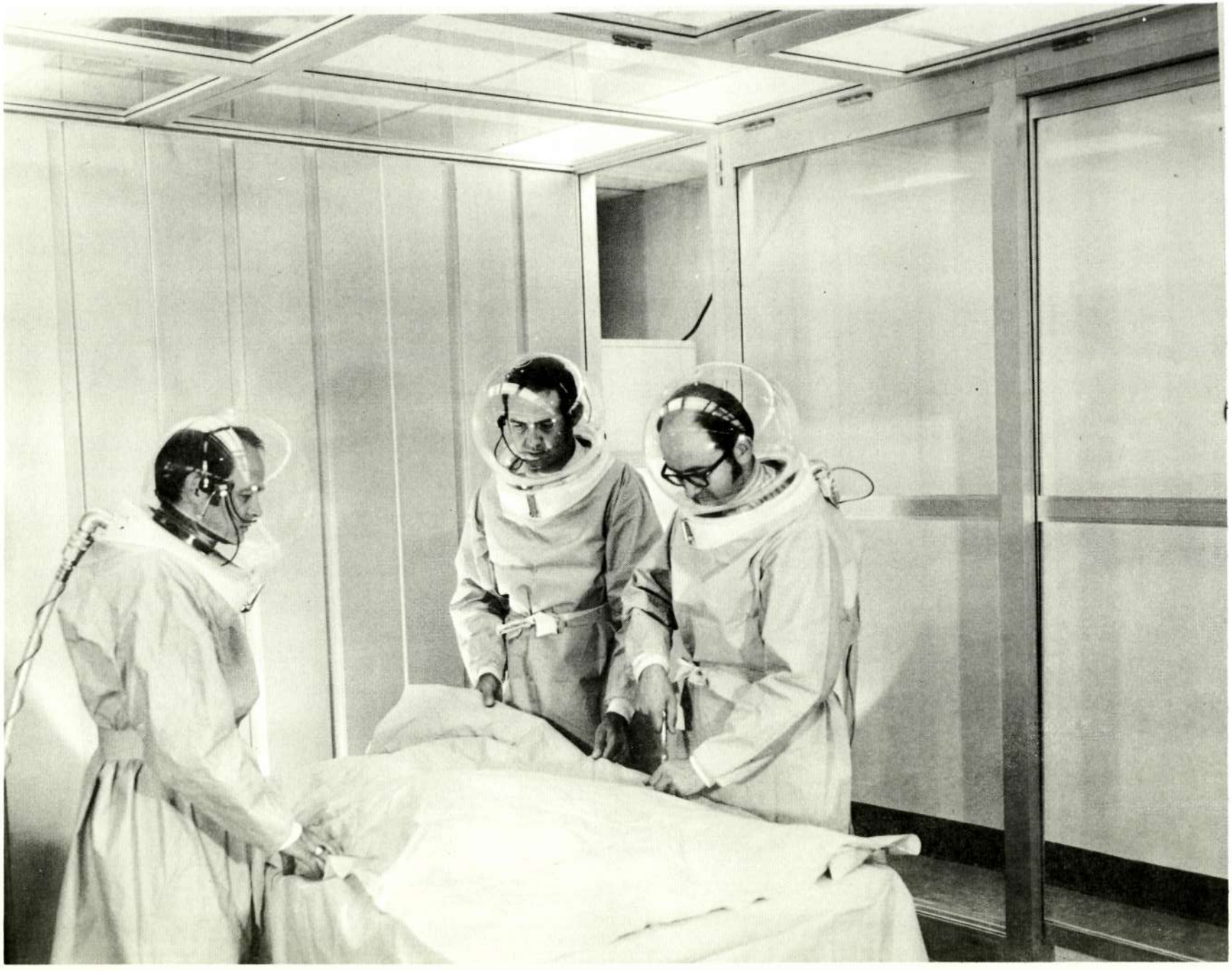

Figure V-7 Surgery Team Simulation

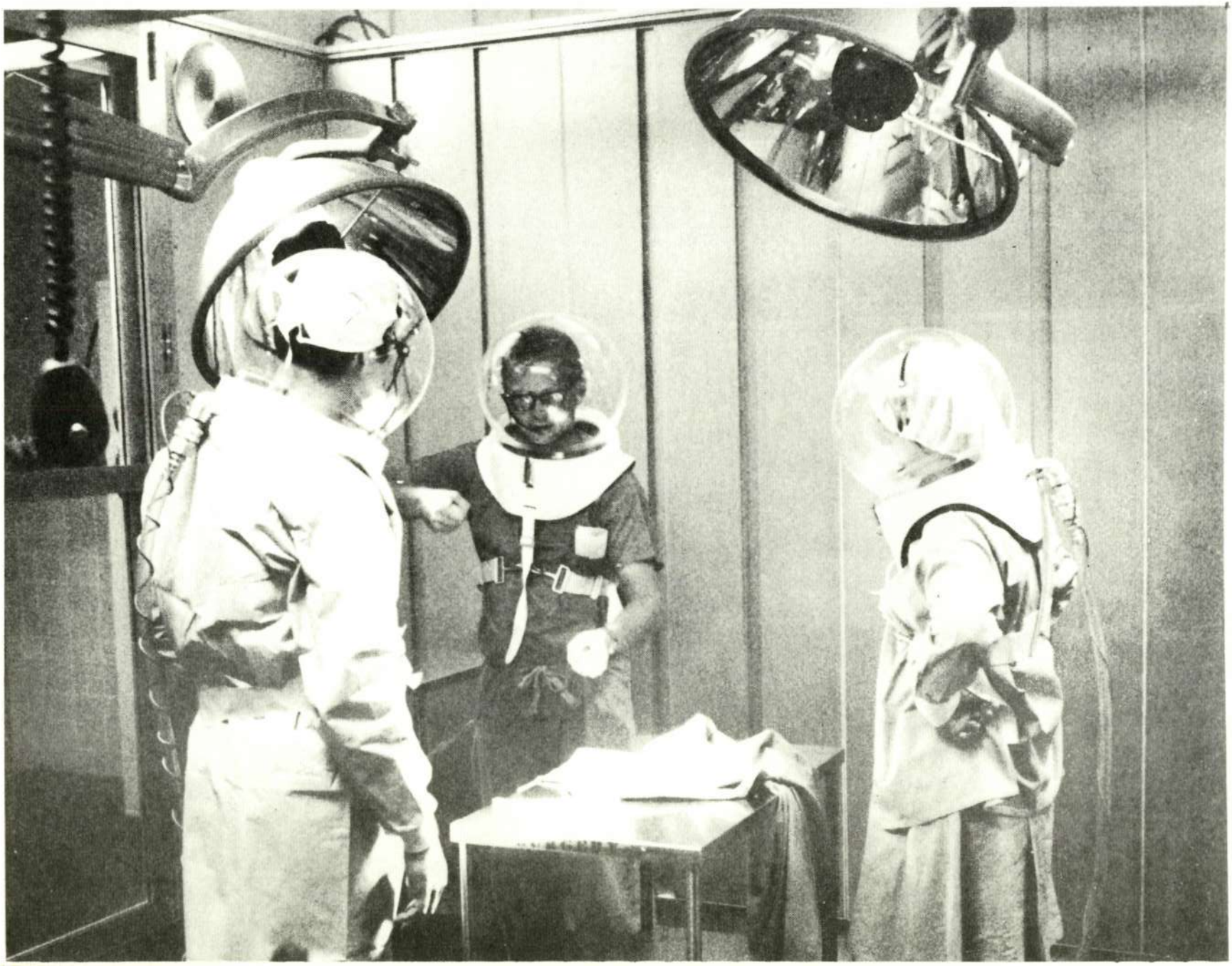

Figure V-8 Surgery Simulation by St. Luke's Personnel

This functional demonstration test verified the following:

a. Tasks could be performed in accordance with the Operating Procedures.

b. Required movements of the surgery team could be performed.

c. The surgery team could adequately communicate.

d. Helmets could be readily removed in the event of an emergency.

e. The total system performed the functions required for its intended use at St. Luke's Hospital.

All acceptance tests were successfully completed. A letter of acceptance of the System by St. Luke's Hospital was obtained on 19 October 1971. The DD-250 was signed 28 October 1971.

VI. DATA COLLECTION AND EVALUATION

A. SYSTEM OPERATIONAL USAGE

During the experimental period the System was used in two modes. The total system including helmets and special gowns were utilized for all operations involving the total replacement of a hip joint. For less complicated surgical procedures, the laminar flow only capability was utilized with standard surgery attire. In general, the procedure was the same for both modes as described in the following paragraphs.

Prior to the patient arrival, the portable clean room blowers are activated. The air is allowed to circulate and be filtered for several minutes. One nurse who has scrubbed and is in standard operating room attire, prepares the back tables by unwrapping instruments and draping materials. When the helmets are to be used, this nurse then leaves the operating suite, dons a shoulder pad and communication system and scrubs again. She is then assisted into her helmet and paper gown and then puts on double sterile gloves.

The patient is transferred from his bed or cart to the operating room table and then into the laminar flow room. The patient is anesthetized and the area of incision prepared in a standard fashion, utilizing an iodinated soap followed by iodinated painting followed by a 70% alcohol wash. Sterile draping of the operative area is then accomplished, and the patient is then moved approximately two feet further into the operating room towards the plenum.

After the patient is brought into the room and sterile preping of the operative area begins, the surgeons start their scrub at the scrub sink with their shoulder pads and communication gear in place when the helmets are to be used. They then proceed into the room and sit on a stool. Hands are dried, and the helmets affixed to the shoulder pads after umbilical and communication connections are made. Paper gowns are then applied and double gloves are worn.

The anesthesiologist is at all times on the downwind side of the wound and he does not wear sterile attire. Generally speaking, two circulating nurses are in the operating area at all times. These personnel always stay downwind of the wound. They may pass extra needed instruments or other material to the scrub nurse or surgeon but they are always in a position downwind and away from the wound area.

The sterile instrument back tables are placed to the sides of the plenum, so as not to cause obstruction between the plenum and the wound. Drapes are kept a few inches off the floor, so as to minimize possible updraft turbulance and secondary contamination of the wound. Every effort is made during the procedure to eliminate scrubbed personnel passing between the wound and plenums. All unsterile equipment is kept downwind of the wound. This equipment includes a suction apparatus, electrocardiographic monitors, air sampling devices, anesthesia equipment, etc.

Figure VI-1 shows the surgeons in helmets during an actual operation. The anaethetist is at the open end of the clean room and downwind of the patient.

Initially, the System was installed in Operating Room #2 at St. Luke's. Due to conflicts with the cardiovascular surgeons, the System was transferred to Operating Room #6. The transfer which utilized the portability and disassembly features of the System was made without incident. Complete disassembly, transfer, and reassembly was accomplished in approximately four hours by two personnel with the exception of filter module de-erection and erection which was done with three people. After relocation, the laminar flow filters were recertified to Federal Standard 209a.

To date the laminar flow portion of the System has been used for an estimated 570 hours and the helmets, gowns, ventilation and communications systems for an estimated 200 hours. With respect to operational usage of the System, the following observations by the surgery personnel were made:

1. There have not been any mechanical or electrical failures.

2. Dust on external surfaces has been essentially non-existant.

3. With the exception of relocating from Operating Room #2 to #6, the portability feature has not been utilized.

4. Communications and helmet ventilation systems have functioned well.

5. Communications between surgery team members have been adequate.

6. To increase the ventilation flow up through the gowns and provide additional cooling effect, some of the surgery team members prefer to tape the helmet hole in the top closed.

7. Helmets and shoulder pads:

    a. Helmets mar and scratch easily.

b. Reflection from lights is an occasional problem. Can generally be corrected by moving the overhead light position.

c. Slight inferior visual distortion especially in the lower helmet area.

d. Air outlet noise is occasionally an annoyance.

e. Fatigue of personnel from attire after several hours of use. Neck and shoulder aching the following day.

f. More shoulder pad stability needed. Probably need a range of sizes or individual fittings.

8. The gowns were provided in the large size only. Preferably for extensive usage a range of sizes should be provided.

9. Initially the personnel required some adjustment to become accustomed to the use of the System and attire. With continued experience, utilization of the total System became easier and less of an encumbrance.

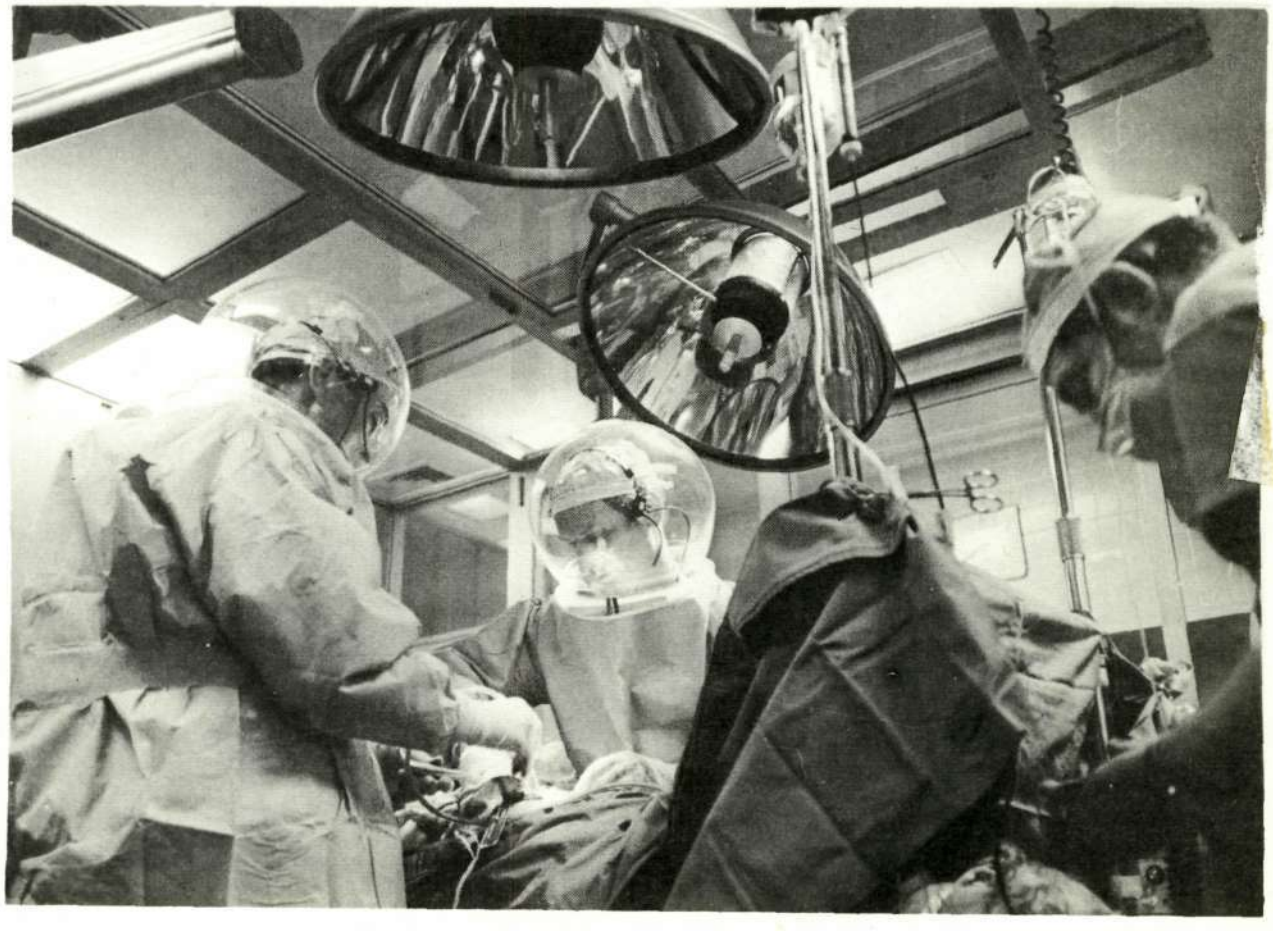

Figure VI-1 System Usage During Actual Surgery

B. DATA COLLECTION

All patients undergoing operative procedures done in the Experimental System were analyzed according to categories on the sample data collection sheet shown in Figure VI-2. Any case in which there was active drainage or recent history of infection in the operative area was excluded in the categories of wound contamination rate, air sampling, and postoperative infection. Any case in which no surgery was performed; that is, only closed manipulation was done, was also excluded for obvious reasons.

Wound cultures were obtained on all clean surgical wounds. Superficial cultures were obtained of the tissues immediately beneath the skin, that is, the subcutaneous fat shortly after incision was made. The culture was, in general, obtained by swabbing the fat around the circumference of the wound. Deep cultures were obtained at the site of operation, namely the joint or bone. These cultures were obtained after reaching the site of operation. In the case where the site of operation lay immediately subjacent to the skin, only deep cultures were obtained. For surgical procedures of concern, "other" cultures were taken. These were additional deep cultures or samples of tissue from the wound site. Generally speaking, the cultures were obtained within 15-20 minutes of making the incision. Cultures were immediately sent to the laboratory where they were plated on blood agar and immersed in thyoglycolate. Cultures were read at 24 and 48 hours by the laboratory personnel. Subsequent data collection was performed by one of the evaluation team members.

Air sampling was done with a Sartorius membrane filter sampling device. Sampling was done at the rate of 28.32 liters per minute (1 cubic foot per minute). The sampler in all cases was located very slightly downstream of the wound itself on the sterile drapes (see Figure VI-3). Samples were taken for 15 minutes per membrane filter. The gelatine filter was initially prepared in the bacteriology laboratory by loading in a clean hood and subsequent gas sterilization. Following exposure, the filters were placed on blood agar media in a clean hood in the bacteriology laboratory and subsequently read at 48 hours.

Records kept of infections during the period of experimentation have been classified as follows:

Superficial - Infections involving only the tissues immediately subjacent to the skin

Deep - Infections involving the area of definitive operation

PATIENT

HOSP. NO.

DATE

DIAGNOSIS

SURGERY

SURGEON

	Yes	No	Organism
CULTURE-Sup.			
CULTURE-Deep			
CULTURE-Oth.			
INFECTION-Sup.			
INFECTION-Deep			TYPE
ANTIBIOTIC			
IRRIGATION			
HEMATOMA			
PRIOR SURGERY			
C.R. - ENVIR.			
C.R. - NASA			
Helmets			
Gowns			Method & Result

AIR SAMPLE

COMMENTS

Figure VI-2 St. Luke's Hospital Record Sheet

An infected wound has been defined as any wound evidencing drainage for more than two to three days or any wound showing signs of redness, swelling or tenderness corroborated by positive wound cultures. Any patient evidencing prolonged fever in the postoperative period was subjected to wound culture.

Records during the experimental period were maintained in Operating Room #6 and the bacteriology laboratory at St. Luke's Hospital. Day-to-day records on patients operated upon in Room #6 at St. Luke's Hospital were kept by the Registered Nurse in charge of that operating room. The data was collected at the end of each month during the experimental period and submitted to Martin Marietta Corporation for submittal in the Monthly Progress Reports.

A summary of all data collected on the System is shown in Appendix A.

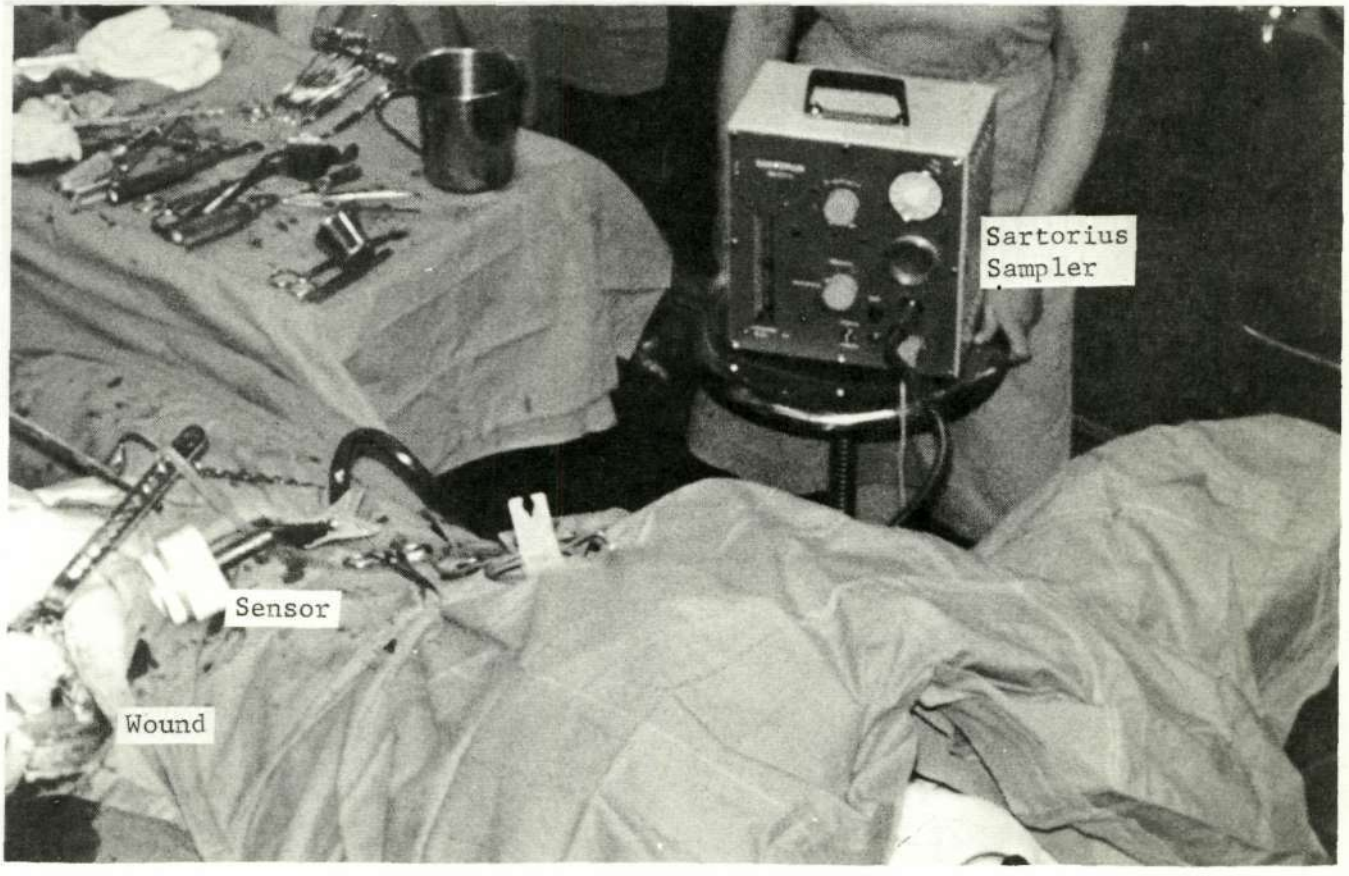

Figure VI-3 Air Sampling Setup

C. EVALUATION

The data collected for the wound cultures, infections and airborne sampling are summarized in Tables VI-1, VI-2 and VI-3. Also shown for comparison is similar data previously collected at St. Luke's for a regular operating room and for an operating room equipped with a similar horizontal laminar flow clean room.

As indicated, 233 operations were performed during the evaluation period. 73 operations utilized the total system and 160 utilized the laminar flow clean room portion only. As previously noted, the total system was primarily used for the total hip replacement surgery.

1. Wound Contamination Rates

Comparison of wound contamination rates reveals that the use of the experimental system clean room itself shows relatively little significant difference in the wound contamination rate when compared to the previous St. Luke's clean room. The rate is 4.3% in the previous clean room compared to 5.2% in the experimental system clean room. While the rate in the latter room is slightly greater and while strict statistical analysis has not been applied, it would appear that these differences are relatively insignificant considering the small data base. Both show a substantial reduction in wound contamination rate compared to a regular operating room which showed an overall rate of 22.0%. The medical evaluation team believes that this is quite significant. It does indicate that the laminar flow clean rooms are effective in reducing airborne contamination of wounds.

When the rates for positive cultures using the total system are considered, the data to date does not indicate a significant reduction in the overall contamination rate. A reduction in the wound contamination rates of the superficial cultures is indicated when compared to both of the laminar-flow-only clean rooms, however the deep wound rates are approximately the same. Certainly, there is a marked reduction in all categories when compared to the regular operating room. It should be pointed out that in comparing the total system results with the other systems it should be kept in mind that the total system was used primarily for the complex total hip joint replacement surgical procedures and would have a greater potential for a positive culture. However, based upon the present data, the evaluation team cannot state that the addition of the helmet and special gown system to the utilization of a laminar flow clean room increases the effectiveness in reducing wound contamination rates.

Culture data on two cases were excluded from consideration in the above data. One case involving bilateral hip surgery with two positive

Table VI-1 Evaluation Data Summary - Wound Cultures

System / Type	No. Cases	No. Cases Cultured	No. Cultures	No. Positive Cultures	Contamin. Rate/ Culture
TOTAL EXPERIMENTAL SYSTEM (HELMETS & GOWNS)					
Superficial		59	59	1	1.7%
Deep Wound		72	72	4	5.6%
Other		8	11	1	9.1%
Overall	73		142	6	4.2%
EXPERIMENTAL SYSTEM LAMINAR FLOW ONLY					
Superficial		96	96	5	5.2%
Deep Wound		148	148	8	5.4%
Other		6	8	0	0
Overall	160		252	13	5.2%
PREVIOUS ST. LUKE'S LAMINAR ROOM (O.R. #8)					
Superficial		119	119	4	3.4%
Deep Wound		237	242	12	5.0%
Other		16	16	0	0
Overall	257		377	16	4.3%
REGULAR O.R.					
Superficial		56	56	10	17.9%
Deep Wound		107	107	25	25.4%
Other		14	14	4	28.6%
Overall	108		177	39	22.0%

Table VI-2 Evaluation Data Summary - Airborne Sampling

System	No. Cases Sampled	Liters Sampled	Cu. Ft. Sampled	No. Bacteria Count	Bacteria per Liter	Bacteria per Cu. Ft.	Remarks
Total Experimental System (Helmets & Gowns)	18	47,889	1691	19	0.0004	0.011	11 of the 18 bacteria occurred in one 15-minute sample which might indicate a contaminated sensor.
Experimental System Laminar Flow Only	4	8,071	285	4	0.0005	0.014	
Previous St. Luke's Laminar Room	5	9,629	340	34	0.0035	0.1	
Regular Operating Room	4	20,220	714	2785	0.1380	3.9	

NOTE: Sampling was taken at a location approximately one inch downstream (with respect to the laminar air flow) of the wound. Sampling was done with a Sartorius Membrane Sampler or a Gelman Impingement Sampler.

Table VI-3 Evaluation Data Summary - Infections

System / Type	No. Cases	From All Sources			Surgically Induced Only	
		No. Infections	Infection Rate/Patient		No. Infections	Infection Rate/Patient
TOTAL EXPERIMENTAL SYSTEM (HELMETS & GOWNS)						
Superficial		3	4.1%		0	0
Deep Wound		0	0		0	0
Other		0	0		0	0
Overall	73	3	4.1%		0	0
EXPERIMENTAL SYSTEM LAMINAR FLOW ONLY				2.1%		
Superficial		2	1.3%		0	0
Deep Wound		0	0		0	0
Other		0	0		0	0
Overall	160	2	1.3%		0	0
PREVIOUS ST. LUKE'S LAMINAR ROOM (O.R. #8)						
Superficial		10	3.9%		-	-
Deep Wound		1	0.4%		-	-
Other		0	0		-	-
Overall	257	11	4.3%		-	-
REGULAR O.R.						
Superficial		5	4.6%		-	-
Deep Wound		0	0		-	-
Other		0	0		-	-
Overall	108	5	4.6%		-	-

superficial and one positive deep wound culture was excluded. It was considered that these wounds were contaminated from adjacent skin areas due to difficulty in preping this patient who had severe flexion contractures of the hips. Clinical infection did not result in this case. One patient had undergone aspiration of the hip preoperatively and several positive cultures for Staphylococcus epidermidis were obtained. Two deep wound cultures were also positive for Staphylococcus epidermidis during the time of surgery. This patient was not included in the consideration because of the pre- and intraoperative cultures. At the time of writing this report, the patient has not developed clinical infection, but the suspicion still remains that he may do this in the future.

2. Air Sampling

Review of data from the regular operating room with regard to wound site sampling reveals an average bacterial count of 0.1380 bacteria/liter of air sampled (3.9 per cubic foot). In the previous St. Luke's clean room this figure has fallen to 0.0035 bacteria/liter (0.1 per cubic foot). In these two areas the Gelman bacterial sampler was utilized. For the sampling in the experimental system, a Sartorius membrane filter sampler was utilized. Comparison of samples taken at the same area using the Gelman and Sartorius samplers have revealed that the results from sampling are quite similar. In general, there was a slightly less positive rate for the membrane sampler.

Review of the data from the experimental system sampling, in conjunction with and without the helmets and special gowns, reveals essentially no difference in the air sampling bacteria rates. These are extremely low (0.0005 bacteria/liter) and are thought to represent statistically insignificance when compared to those found in the regular operating room. As noted, 11 of the 19 bacteria recorded using the total system was counted on one 15-minute sample which might indicate a contaminated membrane. If this sample was discounted, the total system rate would be further reduced to 0.0002 bacteria/liter (0.0048 per cubic foot).

3. Wound Infection Rate

The infection rate data shown in Figure VI-3 is in two categories: 1) infections traceable to the surgical procedure, and 2) infections from all sources including post operative for which data was available from the use of the previous St. Luke's laminar flow clean room and a regular operating room. Unfortunately this previous data was not screened at the time for an infections traceable to surgery category.

As indicated, zero infections were recorded to date that were traceable to the surgical procedure with the use of the experimental system. This is a positive indication for the effectiveness of the system, however, a conclusion of the total system versus the laminar flow portion only cannot be made since both modes reflect zero.

Also, a definite conclusion cannot be made when comparing the infections "from all sources" data. The total system which was used primarily for total hip operations shows a rate of 4.1% and has been preliminarily classified as being from post operative sources. The laminar flow only which was used primarily during less complex surgical procedures reflects 1.3%. The previous St. Luke's data which included all types of orthopedic surgery shows 4.3% for the previous clean room and 4.6% for the regular operating room. A more appropriate comparison to the previous St. Luke's data might be the overall combined experimental system results which would be the 2.1% shown.

During the experimental period, seven post operative incidents did occur. Of these, 2 laminar flow patients and 3 total system patients developed superficial infections. However, none of these were thought to result directly from the time of surgery because of the circumstances and late development. All of these incidents developed after the immediate post operative period and some of them as late as three weeks. All of these wounds subsequently healed without difficulty. These incidents are described as follows:

a. A superficial infection developed ten days following total hip surgery in a patient who had developed pneumonia. When discovered, both an initial sputum and later wound culture showed Staphylococcus aureus, coagulase positive. The wound infection quickly healed with appropriate care. Wound cultures at the time of surgery were negative.

b. A total hip patient had an uneventful course until the superficial layer of the proximal wound separated when the steristrip sutures were inadvertently removed with the dressing at five days. Subsequent cultures showed pseudomonas. The would healed uneventfully.

c. A patient who underwent upper extremity amputation for malignancy initially was healing normally. About two weeks after surgery the patient fell on the wound area and developed a hematoma. This drained and the culture subsequently showed staphylococcus aureus.

d. A total hip patient developed superficial draining sinuses at the point of retention suture entrance. Cultures showed Proteus, an enteric organism. Drainage began eight days following surgery and was thought to be secondary to suture reaction with secondary infection. The wounds subsequently healed completely.

e. A total hip patient became very ill from aspiration into his lungs. He subsequently developed pneumonia. At that time the wound was cultured and pseudomonas was grown. The wound showed no evidence of infection either at that time or later.

f. A bunionectomy wound was dry and healing normally one week following surgery. Three weeks later, it became red, painful and drained. Cultures showed staphylococcus aureus. This was considered to be a late infection secondary to post operative contamination.

g. One total hip patient developed a superficial infection with drainage 12 days following surgery. The culture was an enteric bacteria. Because of the late appearance and the type of organism, this infection is thought to be due to secondary contamination of the wound after surgery.

As noted above, none of these patients were thought to be contaminated primarily at the time of surgery. In the experience at St. Luke's on total hip patients, no example of deep wound infection has developed long after surgery during the past year when using a clean room. It should be pointed out, however, that deep wound infections with implantation surgery may occur up to several years following surgery; and for this reason, final evaluation of infection rates cannot be made at this time.

4. Evaluation Conclusion

It is the conclusion of the evaluation group that this system has been effective in reducing the airborne contamination of the wound. However, the use of the helmets and special gowns may not be a significant part of this protection. Definitive conclusions with regard to the reduction of the incidence of wound infections cannot be made at this time due to the possibility of late developments. The evaluation team found that the use of the system has made the surgery personnel more aware of potential avenues of wound contamination in the operating room. If for no other reason, it has been important and valuable in improving operative care of the wound. The evaluation team believes that further trials with this system are justified and that, with time, this system or modification thereof will become commonplace in operating rooms in the United States.

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APPENDIX A

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Table A-1 Patient Data - **Total Experimental System**

No.	Patient	Date	Surgery	Wound Culture			Positive Cultures			Type of Organism	Remarks
				Super.	Deep	Other	Super.	Deep	Other		
1	A. M.	10/22/71	Total Hip Arthroplasty	1	1						
2	G. P.	10/22/71	Hip Nail	1	1						
3	R. W.	12/30/71	Arthrotomy Left Knee								
4	M. B.	12/30/71	Step Staples Removal Right Knee		1						
5	C. W.	12/30/71	Removal of Neuroma from left Femoral Circumflex		1						
6	D. P.	12/30/71	Right Hip Pinning		1						
7	L. H.	12/31/71	Fractured Right Ankle Repair		1						
8	A. S.	1/3/72	Repair Left Hallux Rigidus		1						
9	A. S.	1/3/72	Repair Right Hallux Rigidus		1						
10	R. S.	1/3/72	Repair Right Index Nerve		1						
11	D. A.	1/3/72	Fractured Left Ankle Repair		1						
12	C. L.	1/3/72	Repair Acromial Clavicular Separation		1						
13	J. M.	1/4/72	Repair Torn Rotator Cuff Right Shoulder		1			1		Micrococcus	
14	W. F.	1/6/72	Total Hip Arthroplasty (Muller)	1	1						
15	M. F.	1/6/72	Hip Nail		1						

APPENDIX A

Table A-1 Patient Data - **Total Experimental System (continued)**

No.	Patient	Date	Surgery	Wound Culture			Positive Cultures			Type of Organism	Remarks
				Super.	Deep	Other	Super.	Deep	Other		
16	M. F.	1/7/72	Removal of Left Moore Prosthesis	1	1	4					
17	J. K.	1/7/72	Hip Nail		1						
18	M. H.	1/7/72	Left Hip Prosthesis	1	1						
19	A. J.	1/10/72	Total Hip Arthroplasty (Charnley)	1	1						
20	J. S.	1/10/72	Total Hip Arthroplasty (Charnley)	1	1						Note 1
21	E. J.	1/12/72	Total Hip Arthroplasty (Charnley)	1	1						
22	E. D.	1/12/72	Insertion of Moore Prosthesis	1	1						
23	R. C.	1/12/72	Staples - Right Knee	1	1						
24	J. W.	1/12/72	Arthrotomy Right Knee	1	1						
25	E. B.	1/13/72	Total Hip Arthroplasty (Muller)	1	1			1		Staphylococcus Epidermitis	
26	G. S.	1/13/72	Total Hip Arthroplasty (Muller)	1	1						
27	W. Z.	1/13/72	Hip Nail		1						
28	B. H.	1/14/72	Total Hip Arthroplasty (Charnley)	1	1						
29	H. L.	1/14/72	Total Hip Arthroplasty (Charnley)	1	1						Note 2
30	M. F.	1/17/72	Total Hip Arthroplasty (Charnley)	1	1						

APPENDIX A

Table A-1 Patient Data - **Total Experimental System (continued)**

No.	Patient	Date	Surgery	Wound Culture			Positive Cultures			Type of Organism	Remarks
				Super.	Deep	Other	Super.	Deep	Other		
31	M. M.	1/20/72	Total Hip Arthroplasty (Muller)	1	1						
32	S. B.	1/20/72	Total Hip Arthroplasty (Muller)	1	1						
33	A. N.	1/28/72	Total Hip Arthroplasty (Charnley)	1	1						
34	F. H.	2/4/72	Total Hip Arthroplasty (Muller)	1	1						
35	A. P.	2/4/72	Total Hip Arthroplasty (Charnley)	1	1						
36	P. K.	2/4/72	Pes Ansernuc Transfer Left Knee	1	1						
37	H. B.	2/9/72	Total Hip Arthroplasty (Charnley)	1	1						
38	E. F.	2/10/72	Total Hip Arthroplasty (Muller)	1	1						
39	H. P.	2/10/72	Total Hip Arthroplasty (Muller)	1	1						
40	M. F.	2/11/72	Total Hip Arthroplasty (Charnley)	1	1						
41	L. T.	2/11/72	Total Hip Arthroplasty (Charnley)	1	1						Note 3
42	G. M.	2/17/72	Total Hip Arthroplasty (Muller)	1	1						
43	C. O.	2/17/72	Total Hip Arthroplasty (Muller)	1	1						
44	A. N.	2/18/72	Total Hip Arthroplasty (Charnley)	1	1	1					
45	C. M.	2/18/72	Total Hip Arthroplasty (Charnley)	1	1						

APPENDIX A

Table A-1 Patient Data - **Total Experimental System (continued)**

No.	Patient	Date	Surgery	Wound Culture			Positive Cultures			Type of Organism	Remarks
				Super.	Deep	Other	Super.	Deep	Other		
46	J. A.	2/21/72	Re-Insertion of Left Muller Femoral Component	1	1	1					
47	H. B.	2/23/72	Total Hip Arthroplasty (Charnley)	1	1						
48	W. A.	2/24/72	Total Hip Arthroplasty (Muller)	1	1	1			1	Staphylococcus Epidermitis	
49	R. F.	2/25/72	Removal of Prosthesis Tot. Hip Arthroplasty (Muller)	1	1						
50	J. S.	2/25/72	Total Hip Arthroplasty (Charnley)	1	1						
51	T. P.	3/1/72	Right Hip Nailing	1	1	1					
52	P. C.	3/8/72	Total Hip Arthroplasty (Charnley)	1	1	1					
53	E. J.	3/9/72	Total Hip Arthroplasty (Muller)	1	1						
54	K. H.	3/9/72	Total Hip Arthroplasty (Muller)	1	1						
55	O. F.	3/10/72	Total Hip Arthroplasty (Charnley)	1	1						Note 4
56	F. K.	3/13/72	Total Hip Arthroplasty (Muller)	1	1						
57	F. R.	3/13/72	Total Hip Arthroplasty (Muller)	1	1						
58	K. H.	3/21/72	Total Hip Arthroplasty (Muller)	1	1						
59	E. P.	3/21/72	Rem. of Moore Prosthesis Total Hip Arthroplasty	1	1	1					
60	H. A.	3/24/72	Total Hip Arthroplasty (Charnley)	1	1	1		1		Hemolytic Streptococcus	

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Table A-1 Patient Data - **Total Experimental System (concluded)**

No.	Patient	Date	Surgery	Wound Culture			Positive Cultures			Type of Organism	Remarks
				Super.	Deep	Other	Super.	Deep	Other		
61	J. S.	3/24/72	Total Hip Arthroplasty (Muller)	1	1						
62	M. G.	3/27/72	Total Hip Arthroplasty (Charnley)	1	1						
63	E. B.	3/29/72	Total Hip Arthroplasty (Charnley)	1	1						
64	V. H.	4/3/72	Total Hip Arthroplasty (Charnley)	1	1						
65	H. K.	4/6/72	Total Hip Arthroplasty (Charnley)	1	1						
66	J. C.	4/6/72	Total Hip Arthroplasty (Charnley)	1	1						
67	T. E.	4/7/72	Total Hip Arthroplasty (Charnley)	1	1		1	1		Staphylococcus Epidermitis	Note 5
68	W. W.	4/11/72	Total Hip Arthroplasty (Muller)	1	1						
69	E. B.	4/12/72	Total Hip Arthroplasty (Muller)	1	1						
70	M. N.	4/13/72	Total Hip Arthroplasty (Muller)	1	1						
71	A. P.	4/13/72	Total Hip Arthroplasty (Muller)	1	1						
72	V. C.	4/18/72	Total Hip Arthroplasty (Muller)	1	1						
73	R. W.	4/20/72	Total Hip Arthroplasty	1	1						
			TOTAL	59	72	11	1	4	1		

NOTES

NOTE 1: One superficial clinical infection occurred, however, it was not considered to be a result of the surgery procedure. The infection developed ten days following surgery in a patient who had developed pneumonia. When discovered, both an initial sputum and later wound culture showed Staphylococcus aureus, coagulase positive. The wound infection quickly healed with appropriate care. Wound cultures at the time of surgery were negative.

NOTE 2: A total hip patient became very ill from aspiration into his lungs. He subsequently developed pneumonia. At that time the wound was cultured and pseudomonas was grown. The wound showed no evidence of infection either at that time or later.

NOTE 3: A total hip patient had an uneventful course until the superficial layer of the proximal wound separated when the steri-strip sutures were inadvertently removed with the dressing at 5 days. Subsequent cultures showed pseudomonas. The wound healed uneventfully.

NOTE 4: A patient developed 3 superficial draining sinuses at the point of retention suture entrance. Cultures showed Proteus, an enteric organism. Drainage began 8 days following surgery and was thought to be secondary to suture reaction with secondary infection. The wounds subsequently healed completely.

NOTE 5: One patient developed a superficial infection with drainage 12 days following surgery. The culture was an enteric bacteria. Because of the late appearance and the type of organism; this infection is thought to be due to secondary contamination of the wound after surgery.

APPENDIX A

Table A-2 Patient Data - **Experimental System, Laminar Flow Only**

No.	Patient	Date	Surgery	Wound Culture			Positive Cultures			Type of Organism	Remarks
				Super.	Deep	Other	Super.	Deep	Other		
1	R. B.	11/5/71	Hip Pin	1	1						
2	F. C.	11/9/71	Carpal Tunnel Release								
3	R. C.	11/9/71	Total Hip Arthroplasty	1	1						
4	J. J.	11/9/71	Torn Knee Ligament Repair		1						
5	L. A.	11/10/71	Hip Nail		1						
6	L. T.	11/10/71	Hip Prosthesis	1	1						
7	H. S.	11/18/71	Bone Graft		1						
8	J. P.	12/28/71	Torn Meniscus Excise		1						
9	T. H.	12/28/71	Patella Tendon Transfer		1						
10	M. B.	12/28/71	Finger Cyst Excise								
11	D. S.	12/29/71	Lumbar Laminectomy	1	1						
12	F. S.	12/29/71	Bankhartt Reconstruction Left Shoulder		1						
13	L. K.	1/3/72	Repair of Torn Left Achilles Tendon								
14	S. K.	1/4/72	Reduction & Fusion Cervical Spine - Bone Graft	1	1		1			Diphtheroids	
15	K. H.	1/5/72	Repair Right Lateral Ligament of Ankle		1						

Table A-2 Patient Data - **Experimental System, Laminar Flow Only (continued)**

No.	Patient	Date	Surgery	Wound Culture			Positive Cultures			Type of Organism	Remarks
				Super.	Deep	Other	Super.	Deep	Other		
16	M. C.	1/5/72	Arthrotomy of Left Ankle		1						
17	W. C.	1/5/72	Arthrotomy of Right Knee		1						
18	W. D.	1/7/72	Arthrotomy of Right Knee		1						
19	T. P.	1/8/72	Right Olecranon-lineback Screw Insertion		1						
20	J. D.	1/8/72	Hip Nail		1						
21	L. N.	1/10/72	Post Polio Encephalitis Elbow Amputation								
22	L. L.	1/11/72	Arthroscopy & Arthrotomy of Right Knee								
23	M. A.	1/11/72	Hip Nail	1	1						
24	W. B.	1/13/72	Suture of Deltoid Ligament		1						
25	H. S.	1/17/72	Hip Plate	1	1	1					
26	W. L.	1/17/72	Excisional Biopsy	1	1						
27	E. P.	1/17/72	Bone Graft to Wrist from Left Iliac Crest								
28	F. A.	1/17/72	Fracture Right Femur - Rod Insertion	1	1						
29	O. W.	1/18/72	Repair Rotator Cuff - Partial Acromionectomy	1	1						
30	H. S.	1/18/72	Tibial Ostectomy	1	1						

Table A-2 Patient Data - **Experimental System, Laminar Flow Only (continued)**

No.	Patient	Date	Surgery	Wound Culture			Positive Cultures			Type of Organism	Remarks
				Super.	Deep	Other	Super.	Deep	Other		
31	C. S.	1/18/72	Arthroscopy & Partial Medial Meniscectomy		1						
32	J. S.	1/18/72	Partial Patellectomy Right Knee	1	1						
33	J. C.	1/19/72	Left Meniscectomy	1	1	2					
34	P. D.	1/19/72	Lumbar Fusion	1	1						
35	H. S.	1/20/72	Reconstruction of Right Shoulder	1	1		1	1		Diptheroids	
36	A. O.	1/20/72	Metatarsal Head Removal		1						
37	M. F.	1/21/72	Renail of Left Hip	1	1						
38	C. W.	1/21/72	Right Hip Release	(1)	(1)		(1)	(1)		Klebsiella Escherichia Coli.	Note 1
39	C. W.	1/21/72	Left Hip Release	(1)	(1)		(1)			Klebsiella	Note 1
40	D. T.	1/25/72	Left Bunionectomy & Steinmann Pin		1						Note 2
41	G. W.	1/25/72	Arthroscopy & Right Medial Meniscectomy	1	1						
42	E. V.	1/26/72	Hip Nail	1	1						
43	A. R.	1/26/72	Excision of Tumor from Distal End of Scapula	1	1						
44	R. H.	1/26/72	Exploratory of Lumbar Spine		1						
45	L. L.	1/26/72	Excision of Martoni Neuroma from Right Foot		1						

Table A-2 Patient Data - **Experimental System, Laminar Flow Only (continued)**

No.	Patient	Date	Surgery	Wound Culture			Positive Cultures			Type of Organism	Remarks
				Super.	Deep	Other	Super.	Deep	Other		
46	E. W.	1/27/72	Hemi-Arthroplasty	1	1	2					
47	D. B.	1/27/72	Arthrotomy of Right Knee	1	1						
48	D. L.	1/28/72	Bankhart Reconstruction of Left Shoulder	1	1						
49	V. V.	1/31/72	Arthrotomy Left Knee Med. Callateral lig. Repair	1	1						
50	P. K.	2/1/72	Repair Ruptured Left Torn Achilles Tendon		1						
51	R. M.	2/1/72	Arthroscopy-Arthrotomy Right Knee	1	1						
52	E. B.	2/2/72	Arthrodesis Intra-Tarsal Left Foot		1						
53	D. K.	2/4/72	Pes-Aneserinus Transfer Right Knee		1						
54	V. M.	2/4/72	Biopsy & Excision of Lesion from Right Humerus	1	1						
55	M. S.	2/4/72	Arthrotomy Left Knee & Shaving of Patella	1	1			1		Staphylococcus Epidermitis	
56	J. P.	2/9/72	Excision of Bursa from Right Foot		1						
57	C. T.	2/10/72	Remove Rush Rod from Left Febula Fracture		1						
58	D. I.	2/10/72	Ostectomy of Right Tibia	1	1			1		Staphylococcus Epidermitis	
59	J. F.	2/10/72	Wire Removal from Past Total Hip	1	1	1	1	1		Staphylococcus Epidermitis	Note 3
60	C. K.	2/11/72	Hip Pinning	1	1						

Table A-2 Patient Data - **Experimental System, Laminar Flow Only (continued)**

No.	Patient	Date	Surgery	Wound Culture			Positive Cultures			Type of Organism	Remarks
				Super.	Deep	Other	Super.	Deep	Other		
61	G. S.	2/11/72	Open Reduction of Fractured Hip - Nail	1	1						
62	N. L.	2/14/72	Excision of Lumbar Disc	1	1						
63	P. G.	2/15/72	Left Patella Tendon Transfer	1	1						
64	C. L.	2/15/72	Open Reduction, Right Tibula & Fibula	1	1	1					
65	D. H.	2/15/72	Removal of Pin from Right Elbow		1						
66	N. K.	2/15/72	Repair of Hammer Toes, Right Foot		1						
67	N. K.	2/15/72	Repair of Hammer Toes, Left Foot		1						
68	E. T.	2/18/72	Remove Shoulder Prosthesis and Reconstruction	1	1						
69	G. B.	2/22/72	Arthroscopy & Arthrotomy of Left Knee		1						
70	G. M.	2/22/72	Left Metatarsal Ostectomy								
71	G. M.	2/22/72	Right Metatarsal Ostectomy								
72	C. D.	2/23/72	Arthrotomy of Left Knee	1	1						
73	D. W.	2/28/72	Arthroscope & Arthrotomy of Right Knee		1						
74	L. M.	2/28/72	Media Tibial Ostectomy Right Knee		1						
75	R. A.	2/28/72	Right Median Nerve Release								

Table A-2 Patient Data - **Experimental System, Laminar Flow Only (continued)**

No.	Patient	Date	Surgery	Wound Culture			Positive Cultures			Type of Organism	Remarks
				Super.	Deep	Other	Super.	Deep	Other		
76	V. M.	2/29/72	Forequarter Amputation		1					Diptheriods	Note 4
77	K. A.	2/29/72	Removal of Right Hip Wires	1	1						
78	M. C.	2/29/72	Removal of Pins, Excision Radial Head Right Elbow								
79	J. B.	3/1/72	Arthrotomy of Right Knee	1	1						
80	M. T.	3/1/72	Right Hip Pin	1	1						
81	R. C.	3/1/72	Arthrotomy of Right Knee	1	1			1		Staphylococcus Epidermitis	
82	J. G.	3/2/72	Repair of Left Ankle Ligaments	1	1						
83	B. S.	3/3/72	Repair of Left Knee Tendon	1	1						
84	H. R.	3/3/72	Left Ulna Nerve Transfer		1						
85	E. P.	3/3/72	Removal of Plate from Left Ulna	1	1						
86	E. V.	3/6/72	Repin Left Hip Fracture	1	1						
87	N. R.	3/7/72	Repair Torn Right Rotator Cuff	1	1						
88	J. M.	3/7/72	Recons. of Med. Collateral Lig. Pes Anserinus Trans.	1	1						
89	J. A.	3/7/72	Left Hammer Toe Correction	1	1						
90	J. A.	3/7/72	Right Hammer Toe Correction	1	1						

Table A-2 Patient Data - **Experimental System, Laminar Flow Only (continued)**

No.	Patient	Date	Surgery	Wound Culture			Positive Cultures			Type of Organism	Remarks
				Super.	Deep	Other	Super.	Deep	Other		
91	R. B.	3/7/72	Lumbar Spinal Fusion	1	1			1		Staphylococcus Epidermitis	
92	W. A.	3/7/72	Evac. Hematoma, Post Op. Total Hip Arthroplasty		1						
93	M. K.	3/8/72	Right Mitchell Ostectomy		1						
94	M. K.	3/8/72	Left Mitchell Ostectomy		1						
95	A. K.	3/9/72	Polycentric Total Knee Arthroplasty	1	1						
96	A. P.	3/9/72	Open Reduct. & Internal Fixation of Left Femor	1	1						
97	D. E.	3/10/72	Repair Lateral Ligament Left Ankle		1						
98	G. P.	3/13/72	Open Reduct. & Internal Fixation Left Medial Malleolus		1						
99	W. M.	3/13/72	Screw Removal from Right Wrist								
100	A. C.	3/14/72	Arthrotomy of Right Knee	1	1		1			Staphylococcus Epidermitis	
101	N. B.	3/14/72	Revision of Right Thumb Amputation		1						
102	F. S.	3/15/72	Osteotomy of Left Radius	1	1						
103	H. W.	3/16/72	Right Hip Pinning	1	1						
104	F. M.	3/16/72	Excision of Sesamoid Bone Right Foot		1			1		Dipheroids	
105	J. B.	3/16/72	Repair Ruptured Achilles Tendon		1						

APPENDIX A

Table A-2 Patient Data - **Experimental System, Laminar Flow Only (continued)**

No.	Patient	Date	Surgery	Wound Culture			Positive Cultures			Type of Organism	Remarks
				Super.	Deep	Other	Super.	Deep	Other		
106	K. M.	3/17/72	Valgus Osteotomy Left Hip	1	1						
107	G. C.	3/17/72	Repair Mal-Union Right Metacarpal		1						
108	J. L.	3/17/72	Resect Mal-Union Fract. Right Middle Finger		1						
109	B. W.	3/17/72	Excision of Bursa Olecranon, Right		1						
110	B. W.	3/17/72	Excision of Bursa Left Patella		1						
111	C. H.	3/20/72	Open Reduction of Left Fractured Elbow	1	1						
112	A. T.	3/20/72	Arthroscopy & Arthrotomy Left Lateral Meniscus	1	1						
113	R. M.	3/20/72	Bankart Reconstruction of Right Shoulder	1	1			1		Bacillus Species	Probably a contaminated sample
114	D. D.	3/20/72	Bone Graft Left Tarsal Metatarsol		1						
115	A. V.	3/21/72	Arthroscopy & Arthrotomy of Left Knee	1	1						
116	H. L.	3/21/72	Suture of Partial Ruptured Right Tricep at Elbow		1						
117	M. K.	3/22/72	Osteotomy of Left Knee	1	1						
118	I. H.	3/22/72	Open Reduction of Left Humerus	1	1						
119	T. C.	3/22/72	Arthrotomy of Left Knee	1	1						
120	C. G.	3/22/72	Removal of Rush Pin from Left Ankle	1	1		1			Chromobacteria	

Table A-2 Patient Data - **Experimental System, Laminar Flow Only (continued)**

No.	Patient	Date	Surgery	Wound Culture			Positive Cultures			Type of Organism	Remarks
				Super.	Deep	Other	Super.	Deep	Other		
121	R. B.	3/24/72	Excision of Osteochondrama from Right Elbow		1						
122	F. B.	3/27/72	Arthrotomy of Right Knee	1	1						
123	E. S.	3/28/72	Left Hip Pinning	1	1						
124	M. S.	3/28/72	Left Patellar Tendon Repair	1	1						
125	M. J.	3/28/72	Remove Wires from Post Total Hip Arthroplasty	1	1						
126	J. T.	3/29/72	Excision of Second Metatarsol Head		1						
127	L. W.	3/30/72	Arthrotomy Right Knee	1	1						
128	M. P.	3/30/72	Left Hip Pinning	1	1						
129	N. H.	3/30/72	Open Reduction of Left Ankle		1						
130	L. M.	4/3/72	Arthrotomy of Left Ankle	1	1						
131	R. L.	4/3/72	Arthrotomy of Left Knee	1	1						
132	M. B.	4/3/72	Left Hip Nail	1	1						
133	M. P.	4/4/72	Left Femur Intermedulary Rod Insertion	1	1						
134	B. V.	4/5/72	Right Hip Moore Prosthesis	1	1						
135	E. M.	4/5/72	Left Mitchell Ostectomy								

Table A- 2 Patient Data - **Experimental System, Laminar Flow Only (continued)**

No.	Patient	Date	Surgery	Wound Culture			Positive Cultures			Type of Organism	Remarks
				Super.	Deep	Other	Super.	Deep	Other		
136	A. W.	4/6/72	Left Medial Menisectomy	1	1						
137	O. R.	4/6/72	Left Triple Arthrodesis	1	1						
138	E. W.	4/7/72	Polycentric Left Total Knee	1	1						
139	P. R.	4/7/72	Lumbar Laminectomy	1	1						
140	T. P.	4/7/72	Hip Nail	1	1	1					
141	D. E.	4/10/72	Refusion Left Ankle	1	1						
142	S. G.	4/10/72	Bankhart Reconstruction Left Shoulder	1	1						
143	P. A.	4/10/72	Open Reduction & Fixation of Left Tibia	1	1						
144	M. S.	4/11/72	Open Reduction Right Finger		1						
145	J. P.	4/12/72	Pan-Arthrodesis Right Ankle	1	1						
146	M. G.	4/12/72	Wire Removal Left Hip	1	1						
147	E. S.	4/13/72	Removal of Moore Prosthesis	1	1						
148	R. B.	4/13/72	Left Knee Polycentric Arthroplasty	1	1						
149	H. W.	4/14/72	Left Hip Nail	1	1						
150	R. D.	4/14/72	Meniscectomy of Left Knee	1	1						

Table A-2 Patient Data - **Experimental System, Laminar Flow Only (concluded)**

No.	Patient	Date	Surgery	Wound Culture			Positive Cultures			Type of Organism	Remarks
				Super.	Deep	Other	Super.	Deep	Other		
151	N. D.	4/14/72	Left Hip Nail	1	1						
152	R. M.	4/17/72	Excision of Bursa Right Hip	1	1						
153	F. F.	4/17/72	Right Dorsal Bunionectomy		1						
154	A. A.	4/17/72	Right Hip Nail	1	1						
155	J. P.	4/18/72	Bankhart Reconstruction of Left Shoulder	1	1						
156	M. V.	4/18/72	Arthrotomy Right Knee	1	1						
157	M. C.	4/19/72	Amputation of Fifth Left Toe		1						
158	G. W.	4/19/72	Open Reduction of Left Olecran	1	1						
159	S. K.	4/19/72	Repair Hammer Toe Left Foot		1						
160	T. C.	4/20/72	Excision of Calcified Deposite Left Shoulder	1	1						
			TOTAL	96	148	8	5	8			

NOTES

NOTE 1: One surgical case involving bilateral hip surgery is not included in the culture data. Surgery was in the groin area and prepping was not adequate due to deformities in the hip areas. Two superficial cultures were positive with Klebsiella and Escherichia coli. One deep wound culture was positive for Escherichia coli. These are enteric organisms (intestinal) and are considered secondary to local contamination. No clinical infection resulted.

NOTE 2: A bunionectomy wound was dry and healing normally one week following surgery. Three weeks later, it became red, painful and drained. Cultures showed staphylococcus aureus. This was considered to be a late infection secondary to post operative contamination.

NOTE 3: One patient had a pre-operative hip aspiration which grew Staphylococcus epidermitis. These organisms also showed up on two deep wound cultures taken during surgery (not shown in culture data). It is suspicioned that a deep infection is developing. Further evaluation is required to attempt to determine if the source of the possible infection was a result of contamination during surgery. If determined a result of surgery, the data shown will change upward.

NOTE 4: A patient who underwent upper extremity amputation for malignancy initially was healing normally. About two weeks after surgery the patient fell and developed a hematoma. This drained and the culture subsequently showed staphylococcus aureus.

APPENDIX A

Table A-3 Airborne Sampling Data

Portion of System in Use	No.	Date	Patient	Sample Volume		No. of Organisms	Bacteria Rate	
				Liters	Cu. Ft.		Per Liter	Per Cu. Ft.
Total System	1	1/7/72	M. F.	1699	60	0	0	0
	2	1/7/72	M. H.	1274	45	0	0	0
	3	1/7/72	J. K.	1274	45	0	0	0
	4	1/13/72	G. S.	1699	60	0	0	0
	5	1/13/72	W. Z.	1699	60	0	0	0
	6	1/14/72	H. L.	2974	105	0	0	0
	7	1/28/72	A. N.	3710	131	1	0.0003	0.008
	8	2/4/72	A. P.	2124	75	0	0	0
	9	2/9/72	H. B.	2124	75	0	0	0
	10	2/11/72	M. F.	3823	135	1	0.0003	0.007
	11	2/18/72	A. N.	1699	60	11	0.0065	0.183
	12	2/23/72	H. B.	2549	90	2	0.0008	0.022
	13	3/8/72	P. C.	1699	60	0	0	0
	14	3/21/72	K. H.	2124	75	0	0	0
	15	3/24/72	H. A.	2124	75	0	0	0
	16	3/24/72	J. S.	4248	150	2	0.0005	0.013
	17	3/27/72	M. G.	2124	75	1	0.0005	0.013
	18	3/29/72	E. B.	2124	75	0	0	0
	19	4/5/72	V. H.	1699	60	1	0.0006	0.017
	20	4/6/72	J. C.	1699	60	0	0	0
	21	4/18/72	V. C.	1699	60	0	0	0
	22	4/20/72	R. W.	1699	60	0	0	0
TOTAL	22			47,887	1691	19	0.0004	0.011
Laminar Flow Only	1	1/28/72	D. L.	2549	90	0	0	0
	2	3/1/72	M. T.	1274	45	0	0	0
	3	3/6/72	E. V.	2124	75	4	0.0019	0.053
	4	3/17/72	K. M.	2124	75	0	0	0
TOTAL	4			8071	285	4	0.0005	0.014